LINKHEALTHCARE

OTC Medicines
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Module 1.0.1 Cover Letter

Re: OM-2014-GL-09789-1

Section 9D(3) Self Assessable Request to amend the labelling artwork for

AUST R 225750 LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION

Dear Sir/Madam,

Link Medical Products hereby submits a Self Assessable Request for the above mentioned product. The change requested is to the product labels and involves the removal of a logo and UK licence number, the relocation of the batch and expiry information to a new reverse panel label, change to printing of batch and expiry prefixes at the time of manufacture, and the adjustment of the cutting line for the carton label. The changes are detailed in the table below.

Current **(Module 1.3.4.1)**	**Proposed** **(Module 1.3.4.2)**	**Reason for change**	**ARGOM change code**
Unit and carton labels include manufacturer logo and UK registration details.	Delete manufacturer logo and UK registration details.	Not required in Australia.	RGR
Batch and Expiry prefixes are pre-printed on the label and are located on the front panel of the carton label.	Relocate the Batch and Expiry information to a new reverse panel label, which includes barcode, prefixes to be printed onto the label at the time of manufacture, and adjust the shape (cutting line) of the carton label.	Manufacturer requires that Batch and Expiry information be printed onto the reverse label at the time of batch manufacture.	LFO
Batch and Expiry prefixes are printed on the unit label	Batch and expiry prefixes removed from pre-printed label and will be printed onto the label at the time of batch manufacture.	Manufacturer requires that Batch and Expiry information be printed onto the label at time of batch manufacture.	LFO

Assurance is given that no aspects of the labelling, PI, CMI, pharmaceutical data, manufacturing process or other product details have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'.

Link Medical Products Pty Limited ABN 73 060 971 516
5 Apollo Street, Warriewood, NSW 2102
(T): 02 8401 9777
(F): 02 8401 9788
(E): info@linkhealthcare.com.au
(W): www.linkhealthcare.com.au

LINKPHARMA
LINKMEDICAL TECHNOLOGIES

A copy of the current approved labels are provided in Module 1.3.4.1, marked up labels in Module 1.3.4.2 and the proposed new labels have been provided in Module 1.3.4.3.

A credit card authorisation for $1445.00 for this Request will be faxed directly to the Office of Corporate Services.

This application is complete and contains the required documentation to support this Request, however should you have any questions, please contact me directly by email at s 22 @linkhealthcare.com.au.

Yours sincerely,

s22

02 Oct 14.

s22

Senior Regulatory Affairs Associate
Link Medical Products Pty Ltd

Application General

TGA eBS

Proposed Product name:	LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION
Client Name:	Link Medical Products Pty Ltd T/A Link Pharmaceuticals
Sponsor Name:	Link Medical Products Pty Ltd T/A Link Pharmaceuticals
Contact Person:	s22 [redacted]
Contact Telephone:	s22 [redacted]
Contact Facsimile:	
Contact Email:	s22 [redacted]
This application is to:	change a current ARTG entry
AUST R:	225750
Submission Cost:	$1445
Payment Exemption No:	
Application Status:	Passed Validation
Application Type:	C1

CHANGE DETAILS

Change Category:	Label changes (including package insert)
Change Type:	RGR - Removal of Graphic (other than specified in SSP)
Assurances:	05) No aspects of the labelling, PI, CMI pharmaceutical data, manufacturing process or other product details have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'. L) A copy of the current label of the goods plus a draft copy of the new label, with the relevant changes highlighted, have been supplied.
Change Category:	Label changes (including package insert)
Change Type:	LFO: Reformatting of pre-existing text (ie. moving of blocks of text and not rewording - see LIW, LRT)
Assurances:	05) No aspects of the labelling, PI, CMI pharmaceutical data, manufacturing process or other product details have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'. L) A copy of the current label of the goods plus a draft copy of the new label, with the relevant changes highlighted, have been supplied.
Validation Report:	2/10/14 8:34 AM

Failure Messages

No Failure Messages.

Other Regulatory Requirements

Electronic document/s attached. **Please print a copy of the this application and submit it to the TGA with your**

data and payment

Manufacturer Information

The Manufacturer Martindale Pharmaceuticals is restricted to the manufacture of Registered Therapeutic Good.

Changes made

With this application, is the sponsor seeking a brand equivalence statement for the purpose of Pharmaceutical Benefits Scheme (PBS) Listing:	No
Is the product intended to replace an existing ARTG entry:	No
Proposed Therapeutic Indications:	1. Preparation of nasal mucosa for surgery or endoscopy. ,2. Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose. ,3. Topical anaesthesia prior to indirect or direct laryngoscopy ,4. Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.
Additional Appliance:	

PRODUCT DETAILS

Dosage Form:	Spray, nasal
Visual Identification of Dosage Form:	The drug product is a clear, colourless, sterile solution.
Route of Administration:	Nasal
Method(s) of Sterilisation:	Steam
Container Type:	Vial

PRODUCT CONTAINER And SHELF LIFE DETAILS

Container Condition:	Closed
Container Material:	Glass Type I Clear
Container Closure:	Neither child resistant closure nor restricted flow insert
Proposed Storage Life:	24 Months
Proposed Storage Condition:	Protect from Light
Proposed Storage Temperature:	Store below 25 degrees Celsius
Additional Shelf Life Info:	

PACK SIZE AND POISON SCHEDULE

Pack Size:	2.5 mL
Poison Schedule:	(S2) Pharmacy Medicine

FORMULATION DETAILS

ACTIVE INGREDIENTS:

STANDARD

Ingredient: Lignocaine hydrochloride 125 mg
Specification:
Animal Origin?: No

Ingredient: Phenylephrine 12.5 mg
Specification:
Animal Origin?: No

EXCIPIENT INGREDIENTS:

STANDARD

Ingredient: Water for injections 2.5 mL
Specification:
Animal Origin?: No

Ingredient: Hydrochloric acid 0 QS
Specification:
Animal Origin?: No

Ingredient: Sodium hydroxide 0 QS
Specification:
Animal Origin?: No

MANUFACTURER DETAILS

Name: Martindale Pharmaceuticals
ID: 24472
Clearance ID: MI-2014-CL-00899-1
Location: Bampton Road Harold Hill Romford Essex RM3 8UG
Manufacturing Steps: Manufacture of dosage form
Packaging and labelling
Release for supply
Secondary packaging
Sterilisation
Testing chemical and physical
Testing microbial

ELECTRONIC SUPPORTING ATTACHMENT LIST

Attachments: Table of Contents - m1-1-toc.pdf

Current approved labelling - 1.3.4.1 Current approved labelling.pdf

Marked-up labelling - 1.3.4.2 Marked up labelling.pdf

Proposed labelling - 1.3.4.3 Proposed labelling.pdf

Letter of Application - m1-0-1-letter-applic.pdf

LINKHEALTHCARE

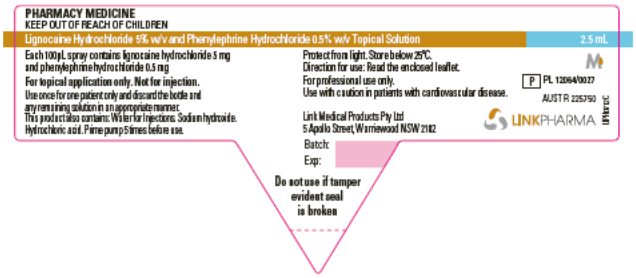
Section 9D(3) Self Assessable Request to amend the labelling artwork for

AUST R 225750 LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION

Module 1.1 Table of Contents (ToC)

Module	Document	CTD folder or file name
1.0.1	Cover letter	m1-0-1-letter-applic
1.1	Table of Contents	m1-1-toc
1.3.4	Current and proposed labelling artwork	m1-3-4-label-mock-up
1.3.4.1	Current approved artwork	1.3.4.1 current approved labelling.pdf
1.3.4.2	Marked up artwork	1.3.4.2 marked up labelling.pdf
1.3.4.3	Proposed new artwork	1.3.4.3 proposed labelling.pdf

Link Medical Products Pty Limited ABN 73 010 971 516
5 Apollo Street, Warriewood, NSW 2102
(T): 02 8401 9777
(F): 02 8401 9788
(E): info@linkhealthcare.com.au
(W): www.linkhealthcare.com.au



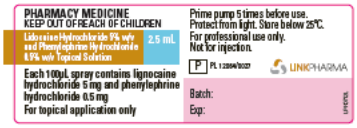
LINKPHARMA

DEVELOPMENT ARTWORK

Component Code: LIPH0712C
Nominal dimensions (mm):
113 x 50 overall
Cutter Profile:

Version Control	Date	By
Version A:	25/07/12	GR
Version B:	14/08/12	GR
Version C edited:	06/08/14	GR
Version D:		
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
PMS 305 C	
PMS 139 C	
PMS 423 C	
Varnish Free Area	



LINKPHARMA

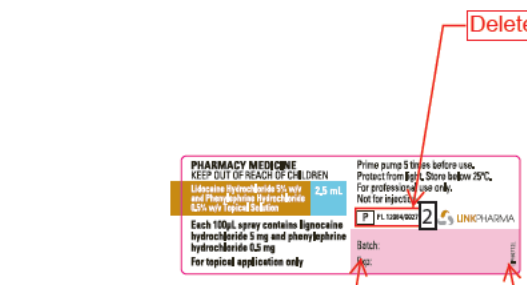
DEVELOPMENT ARTWORK

Component Code: LPH0712L

Nominal dimensions (mm):
132 x 50 overall
Cutter Profile:

Version Control	Date	By
Version A created:	18/11/10	AC
Version B created:	14/08/12	AC
Version C edited:	08/05/13	GR
Version D edited:	25/03/14	GR
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
PMS 305 C	
PMS 139 C	
Varnish free area:	



Delete 1

Move this number up and out of varnish free area 3

Delete Batch: and Exp: (this will be printed onto the label at the time of product batch manufacture). 4

LINKPHARMA

DEVELOPMENT ARTWORK

Component Code: LPH0712L

Nominal dimensions (mm):
132 x 50 overall
Cutter Profile:

Version Control	Date	By
Version A created:	18/11/10	AC
Version B created:	14/08/12	AC
Version C edited:	08/05/13	GR
Version D edited:	25/03/14	GR
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
PMS 305 C	
PMS 139 C	
PMS 423 C	
Varnish free area:	

Summary of Comments on Document 1.PDF

Page: 10

Number: 1 Author: s22 Subject: Callout Date: 30/09/2014 10:23:42 AM +10'00'

Delete

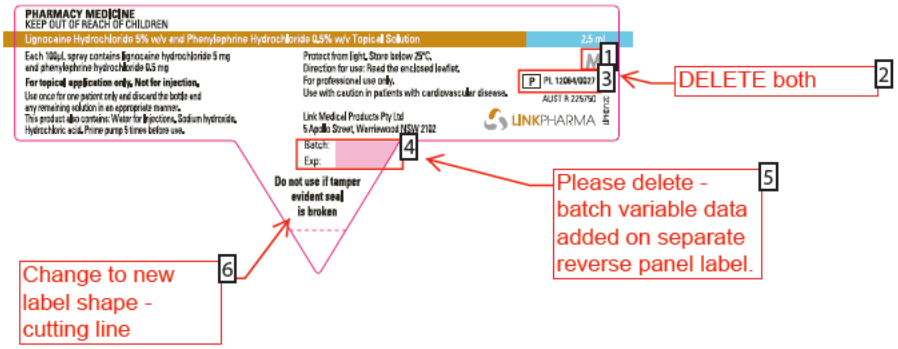
Number: 2 Author: s22 Subject: Rectangle Date: 19/09/2014 1:13:41 AM +10'00'

Number: 3 Author: s22 Subject: Callout Date: 30/09/2014 10:17:58 AM +10'00'

Move this number up and out of varnish free area

Number: 4 Author: s22 Subject: Callout Date: 30/09/2014 10:18:20 AM +10'00'

Delete Batch: and Exp: (this will be printed onto the label at the time of product batch manufacture).



100mm MEASUREMENT VERIFICATION BAR

LINKPHARMA

DEVELOPMENT ARTWORK

Component Code: LIPH0712C
Nominal dimensions (mm):
113 x 50 overall
Cutter Profile:

Version Control	Date	By
Version A:	25/07/12	GR
Version B:	14/08/12	GR
Version C edited:	06/08/14	GR
Version D:		
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
PMS 305 C	
PMS 139 C	
PMS 423 C	
Varnish Free Area	

Page: 11

Number: 1 Author: s22 Subject: Rectangle Date: 19/09/2014 1:17:05 AM +10'00'

Number: 2 Author: s22 Subject: Callout Date: 19/09/2014 1:17:33 AM +10'00'

DELETE both

Number: 3 Author: s22 Subject: Rectangle Date: 19/09/2014 1:17:00 AM +10'00'

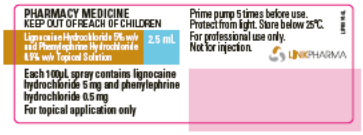
Number: 4 Author: s22 Subject: Rectangle Date: 19/09/2014 1:17:59 AM +10'00'

Number: 5 Author: s22 Subject: Callout Date: 30/09/2014 10:22:22 AM +10'00'

Please delete - batch variable data added on separate reverse panel label.

Number: 6 Author: s22 Subject: Callout Date: 30/09/2014 10:23:01 AM +10'00'

Change to new label shape - cutting line



LINKPHARMA

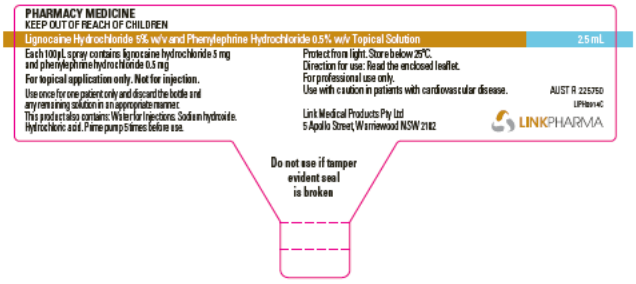
DEVELOPMENT ARTWORK

Component Code: LIPH0914L

Nominal dimensions (mm):
132 x 50 overall
Cutter Profile:

Version Control	Date	By
Version A:	18/11/10	AC
Version B:	14/08/12	AC
Version C:	08/05/13	GR
Version D edited:	30/09/14	GR
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
PMS 305 C	
PMS 139 C	
Varnish free area:	



LINKPHARMA

DEVELOPMENT ARTWORK

Component Code: LIPH0914C

Nominal dimensions (mm):
113 x 50 overall
Cutter Profile:

Version Control	Date	By
Version A:	25/07/12	GR
Version B:	14/08/12	GR
Version C:	06/08/14	GR
Version D edited:	30/09/14	GR
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
PMS 305 C	
PMS 139 C	
PMS 423 C	
Varnish Free Area	

LINKPHARMA

DEVELOPMENT ARTWORK

Component Code: LIPH0914L2
Nominal dimensions (mm):
60 x 20
Cutter Profile:

Version Control	**Date**	**By**
Version A:	29/09/14	GR
Version B:		
Version C:		
Version D:		
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		
Version P:		

Colour Specifications	
Pantone Ref:	Swatch:
PMS Black C	
Varnish free area:	

From: s22
To: s22
Subject: RE: OM-2014-01226-1 -C1 - Request for amended cover letter for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION [SEC=UNCLASSIFIED]
Date: Thursday, 9 October 2014 9:38:52 AM
Attachments: s22 .vcf
20141009 1.0.1 Replacement Cover letter.pdf

Dear s22
Please find attached a replacement cover letter for this application.

The Application Level (C1) has been added into the tabulated detailed description of the proposed labelling changes. The application number has also been corrected (the draft number was included by mistake in the original letter).

Kind regards,
s22

LINKHEALTHCARE
PRETORIA SYDNEY SINGAPORE AUCKLAND TOKYO HONG KONG
s22
Senior Regulatory Affairs Associate
(T): +61 (2) 8401 9777
(F): +61 (2) 8401 9786
(E): s22 @linkhealthcare.com.au
I am in the office Mon/Tue/Thu/Fri

From: s22 @tga.gov.au]
Sent: Wednesday, 8 October 2014 1:37 PM
To: s22
Subject: OM-2014-01226-1 -C1 - Request for amended cover letter for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION [SEC=UNCLASSIFIED]

Dear s22

RE: Administrative check of OTC application

I refer to your application to vary the registration of AUST R 225750 .

On 15 April 2013, the TGA commenced the staged implementation of the new OTC business process. The ARGOM Guidelines on the pre-market application and evaluation process for OTC medicines, which came in to effect with the new business process, state the new administrative requirements for OTC applications. The OMA (Application Entry Team) performs an initial administrative check of each submission received.

Your application has been checked for compliance with the new administrative requirements. The following issues have been identified and must be rectified within seven days in order for your application to proceed.

1. The application level has not been identified. Guidance on determining the correct application level and supporting information required for OTC medicines submissions is available on the TGA website. Please provide the following:
    a. An updated cover letter that clearly states the nature and scope of the application, the application level (as per the OTC application categorisation framework), the reason for selecting the application level and any relevant background information.
    b. For applications to change an OTC medicine, please also provide a description of the change(s) and the reason for the change given. It is not sufficient to restate the change codes that are applicable.

Your application will be placed on stop clock until this documentation is received.

Regards

s22 [redacted]
Departmental Officer
Application Entry & Support
Office of Medicines Authorisation

Phone: s22 [redacted]
Email: s22 [redacted]@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

LINKHEALTHCARE

OTC Medicines
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Module 1.0.1 Cover Letter

Re: OM-2014-01226-1-C1

Section 9D(3) Self Assessable Request to amend the labelling artwork for

AUST R 225750 LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION

Dear Sir/Madam,

Link Medical Products hereby submits a Self Assessable Request for the above mentioned product. The change requested is to the product labels and involves the removal of a logo and UK licence number, the relocation of the batch and expiry information to a new reverse panel label, change to printing of batch and expiry prefixes at the time of manufacture, and the adjustment of the cutting line for the carton label. The changes are described in detail in the table below.

Current (Module 1.3.4.1)	**Proposed (Module 1.3.4.2)**	**Reason for change**	**ARGOM change code**	**Application Level**
Unit and carton labels include manufacturer logo and UK registration details.	Delete manufacturer logo and UK registration details.	Not required in Australia.	RGR	C1
Batch and Expiry prefixes are pre-printed on the label and are located on the front panel of the carton label.	Relocate the Batch and Expiry information to a new reverse panel label, which includes barcode, prefixes to be printed onto the label at the time of manufacture, and adjust the shape (cutting line) of the carton label.	Manufacturer requires that Batch and Expiry information be printed onto the reverse label at the time of batch manufacture.	LFO	C1
Batch and Expiry prefixes are printed on the unit label	Batch and expiry prefixes removed from pre-printed label and will be printed onto the label at the time of batch manufacture.	Manufacturer requires that Batch and Expiry information be printed onto the label at time of batch manufacture.	LFO	C1

Link Medical Products Pty Limited ABN 73 080 971 516
5 Apollo Street, Warriewood, NSW 2102
(T) 02 8401 9777
(F) 02 8401 9788
(E) info@linkhealthcare.com.au
(W) www.linkhealthcare.com.au

LINKPHARMA
LINKMEDICAL TECHNOLOGIES

Assurance is given that no aspects of the labelling, PI, CMI, pharmaceutical data, manufacturing process or other product details have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'.

A copy of the current approved labels are provided in Module 1.3.4.1, marked up labels in Module 1.3.4.2 and the proposed new labels have been provided in Module 1.3.4.3.

A credit card authorisation for $1445.00 for this Request will be faxed directly to the Office of Corporate Services.

This application is complete and contains the required documentation to support this Request, however should you have any questions, please contact me directly by email at s 22 @linkhealthcare.com.au.

Yours sincerely,

s22

09oct14.

s22

Senior Regulatory Affairs Associate
Link Medical Products Pty Ltd

From: s22
To: s22
Subject: RE: OM-2014-01226-1 - C1 - Request for details on labelling for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION [SEC=UNCLASSIFIED]
Date: Thursday, 9 October 2014 10:00:11 AM
Attachments: s22 .vcf
1.3.4.3 Proposed labelling.pdf

Dear s22

The original approved carton label was a single label to be pre-printed, then at the time of manufacture the label was to be imprinted with batch variable data (batch number and expiry date) and then attached to the front panel of a hard plastic container or 'carton'.

The proposed carton label is to be pre-printed and attached to the front panel of the carton. However, the batch variable data (batch number and expiry date) is to be imprinted onto a new and separate carton label (pre-printed with the barcode) which is then to be attached to the reverse panel of the carton.

Please refer to Module 1.3.4.3 (copy attached) in which a clean copy of all three proposed labels are presented. The proposed new reverse panel label is on page 3 of this file.

Kind regards,
s22

LINKHEALTHCARE
PRETORIA SYDNEY SINGAPORE AUCKLAND TOKYO HONG KONG
s22
Senior Regulatory Affairs Associate
(T): +61 (2) 8401 9777
(F): +61 (2) 8401 9786
(E): s22 @linkhealthcare.com.au
I am in the office Mon/Tue/Thu/Fri

From: s22 @tga.gov.au]
Sent: Wednesday, 8 October 2014 2:50 PM
To: s22
Subject: FW: OM-2014-01226-1 - C1 - Request for details on labelling for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION [SEC=UNCLASSIFIED]

Dear s22

Can you please explain what you mean when you indicate on your labelling 'batch variable data added on separate reverse panel label'. You have not provided any other carton label.

Kind regards

s22
Departmental Officer
Application Entry & Support

Office of Medicines Authorisation

Phone: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @tga.gov.au]
Sent: Wednesday, 8 October 2014 1:37 PM
Subject: OM-2014-01226-1 -C1 - Request for amended cover letter for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION [SEC=UNCLASSIFIED]

Dear s22

RE: Administrative check of OTC application

I refer to your application to vary the registration of AUST R 225750 .

On 15 April 2013, the TGA commenced the staged implementation of the new OTC business process. The ARGOM Guidelines on the pre-market application and evaluation process for OTC medicines, which came in to effect with the new business process, state the new administrative requirements for OTC applications. The OMA (Application Entry Team) performs an initial administrative check of each submission received.

Your application has been checked for compliance with the new administrative requirements. The following issues have been identified and must be rectified within seven days in order for your application to proceed.

1. The application level has not been identified. Guidance on determining the correct application level and supporting information required for OTC medicines submissions is available on the TGA website. Please provide the following:
    a. An updated cover letter that clearly states the nature and scope of the application, the application level (as per the OTC application categorisation framework), the reason for selecting the application level and any relevant background information.
    b. For applications to change an OTC medicine, please also provide a description of the change(s) and the reason for the change given. It is not sufficient to restate the change codes that are applicable.

Your application will be placed on stop clock until this documentation is received.

Regards

s22
Departmental Officer
Application Entry & Support
Office of Medicines Authorisation

Phone: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22
To: s22 @linkhealthcare.com.au
Subject: OM-2014-01226-1- C1 Level application - Approval letter [SEC=UNCLASSIFIED]
Date: Thursday, 16 October 2014 11:25:07 AM
Attachments: OM-2014-01226-1 - C1 Level applicaion - Approval letter - ss. 9D(3).pdf

---

Dear Sponsor

Please find attached an electronic copy of the approval letter for your C1 Level application (Submission ID: OM-2014-01226-1).

Regards

s22
Departmental Officer
Application Entry & Support
Office of Medicines Authorisation

Phone: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

s22
Departmental Officer
Application Entry & Support
Office of Medicines Authorisation

Phone: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

Document 4

Australian Government

Department of Health
Therapeutic Goods Administration

File No.: 2013/014736
Submission No.: OM-2014-01226-1

The Managing Director
Link Medical Product s Pty Ltd T/A Link Pharmaceuticals
s22
WARRIEWOOD NSW 2102

Attention: s22
Senior Regulatory Affairs Associate

Dear Sir/Madam

REQUEST UNDER s. 9D(3) FOR VARIATION TO THE ENTRY IN THE ARTG

I refer to your request under subsection 9D(3) of the *Therapeutic Goods Act 1989* (the Act) dated 2 October 2014 to vary the entry of **LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION AUST R 225750** (the Product) in the Australian Register of Therapeutic Goods (the ARTG) as follows:

- remove the manufacturer logo and UK registration details from the carton label
- relocate the batch and expiry information to the reverse panel label of the carton label
- reformat the tamper evident seal shape of the cutting line

Subsection 9D(3) of the Act can be found online at the following link:
http://www.comlaw.gov.au/Details/C2014C00410

Decision

As delegate of the Secretary of the Department of Health, I am, under subsection 9D(3) of the Act, varying the entry of the product in the ARTG as requested on the basis that the variation does not indicate any reduction in quality, safety or efficacy of the product/s for the purposes for which they are to be used.

Review rights

Details of review rights for the decision under subsection 9D(3) are provided at **Attachment 1.**

Please do not hesitate to contact me if you have any further queries regarding this matter.

Yours faithfully

s22 [redacted]

s22 [redacted]
Office of Medicines Authorisation
Market Authorisation Group
Delegate of the Secretary

10 October 2014

Attachments:

1. Review rights

Attachment 1

Review Rights

The decision under subsection 9D(3) of the Act is an "initial decision" within the meaning of section 60 of the Therapeutic Goods Act 1989 (the Act). This means that if your interests are affected, you may seek reconsideration by the Minister. Any request for reconsideration should be made in writing within 90 days after this notification is received and should be sent to the following address:

Assistant Minister for Health
Parliament House
CANBERRA ACT 2600

The letter should be headed "REQUEST FOR RECONSIDERATION UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".

What you should provide in support of your request for reconsideration

It is important that you include with your request any information in support of the request that you would like the Minister to consider. Under subsection 60(3A) of the Act, the Minister is not able to consider any information that you provide after the making of the request unless the information is provided in response to a request from the Minister or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable. To facilitate the consideration of your request it is also requested that you:

1. include a copy of the decision you want reconsidered;
2. describe with as much specificity as you can, exactly what parts of the decision you believe are incorrect or in relation to which you object, and set out the reasons;
3. identify the parts of the information you provide in support of the request that relate to each of those reasons; and
4. if the decision does not relate to you or your company, describe how your interests are affected by the decision.

The Minister may either personally deal with the request or send it to be dealt with by one of the Minister's delegates within the Department. If you are dissatisfied with the result of the decision on the reconsideration request then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of that decision.

From: s22
To: s22
Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]
Date: Friday, 6 February 2015 2:23:05 PM
Attachments: image001.png
image002.jpg
32p5.1 specification 5 feb v1 15 clean.pdf
s22 .vcf

Dear s22

Thank you for your reply. I am pleased to advise that the proposed solution to this issue is acceptable.

The affected product is: AUST R 225750 LIGNOCAINE HYDROCHLORIDE 5% W/V % PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION (File No: 2013/014736).

Copy of the corrected finished Drug Product Specification is attached. Please note the manufacturer has elected to state the specification in terms of 0.100g rather than 100mg :

Current **(Module 3.2.P.5.1)**	**Corrected** **(Module 3.2.P.5.1)**
Spray weight Mean of 15 measurements ± 10% of 100.0µg (90.0-110.0 µg). No individual measurement > ± 15% of 100.0µg (85.0-115.0 µg).	Spray weight Mean of 15 measurements ± 10% of 0.100g (0.90-0.110g). No individual measurement > ± 15% of 0.100g (0.085-0.115g).

Thanks and kind regards,
s22

s22
I am in the office Mon/Tue/Thu/Fri

From: s22 @tga.gov.au]
Sent: Friday, 6 February 2015 12:43 PM
To: s22
Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

Dear s22

I have been asked to respond to your enquiry below.

The case that you have described seems straightforward, and no formal regulatory action should be needed.

If you can provide me with the details of the affected product(s), and with the corrected specification document, I will place the corrected document on file.

Let me know if this will be acceptable to you.

Regards,
s22

s22
Senior Evaluator
OTC Medicines Evaluation Section
Medicines Authorisation Branch

Phone: s22 Fax: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Australian Government Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @linkhealthcare.com.au]
Sent: Friday, 23 January 2015 9:24 AM
To: OTC Medicines
Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

Hi s22
Thank you for your quick reply.

The typographical error is in the units of the specification for the spray weight : µg is incorrect and should read mg. It is suspected the typo came about because the spray volume is 100µL, but the spray weight is 100mg. There is no change to the actual specification for the finished product because the spray weight has always been 100mg.

Current **(Module 3.2.P.5.1)**	**Proposed** **(Module 3.2.P.5.1)**
Spray weight Mean of 15 measurements ± 10% of 100.0µg (90.0-110.0 µg). No individual measurement > ± 15% of 100.0µg (85.0-115.0 µg).	Spray weight Mean of 15 measurements ± 10% of 100.0mg (90.0-110.0 mg). No individual measurement > ± 15% of 100.0mg (85.0-115.0 mg).

Kind regards,
s22

From: s22 @tga.gov.au] **On Behalf Of** OTC Medicines
Sent: Friday, 23 January 2015 9:14 AM
To: s22
Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

HI s22

Could you please advise the type of typographical error? Does it involve actual limits?

s22

OTC Medicines
Application Management & Export
Medicines Authorisation Branch
Phone: s 22
Email: otc.medicines@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22 @linkhealthcare.com.au]
Sent: Friday, 23 January 2015 9:02 AM
To: OTC Medicines
Subject: Request advice on procedure to correct an error

Dear Sir or Madam,
Please may I request advice on how to proceed to correct a typographical error in the finished product specification of an approved OTC medicine?

Kind regards,
s22

s22

I am in the office Mon/Tue/Thu/Fri

LINKPHARMA	Lignocaine HCl 5% w/v and Phenylephrine HCl 0.5% w/v Topical Solution

3.2.P.5.1 Specification(s)

The finished product specification is summarised below:

At release

Test	Specification	Method
Appearance	Clear, bright,colourless liquid	Visual inspection
Identification: a) For Lignocaine b) For Phenylephrine c) For Chloride	 a) Blue-green precipitate b) Violet colour c) White precipitate	HSE method
Lignocaine hydrochloride identity	Complies positive	HPLC
Phenylephrine hydrochloride identity	Complies positive	HPLC
Lignocaine hydrochloride assay (% w/v)	4.75 - 5.25% w/v (±5%)	HPLC
2,6-dimethylaniline	50 ppm	HPLC
Phenylephrine hydrochloride assay (% w/v)	0.475 - 0.525% w/v (±5%)	HPLC
m-hydroxybenzaldehyde	5 ppm	HPLC
pH	4.0 - 5.5	HSE
Spray weight	Mean of 15 measurements ± 10% of 0.100 g (0.090-0.110g) No individual measurement > ± 15% of 0.100 g (0.085 -0.115 g)	HSE method
Extractable volume	≥ 2.5mL	BP
Sterility (membrane filtration)	Complies	BP/Ph. Eur

At end of shelf life

Test	Specification	Method
Appearance	Clear, bright, colourless solution	Visual inspection
Lidocaine hydrochloride assay (% w/v)	4.75 - 5.25% w/v (±5%)	HPLC
2,6-dimethylaniline	400 ppm	HPLC
Phenylephrine hydrochloride assay (% w/v)	0.475 - 0.525% w/v (±5%)	HPLC
m-hydroxybenzaldehyde	50 ppm	HPLC
pH	4.0 - 5.5	HSE
Sterility (membrane filtration)	Complies	BP/Ph. Eur

From: s22
To: s22
Subject: RE: TRIM: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]
Date: Monday, 9 February 2015 2:48:55 PM
Attachments: image003.png

Thank you s22
I have put the corrected specification on file (TGA document reference R15/111022).

Regards,
s22

s22
Senior Evaluator
OTC Medicines Evaluation Section
Medicines Authorisation Branch

Phone: s22 Fax: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Australian Government Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @linkhealthcare.com.au]
Sent: Friday, 6 February 2015 2:22 PM
To: s22
Subject: TRIM: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

Dear s22
Thank you for your reply. I am pleased to advise that the proposed solution to this issue is acceptable.

The affected product is: AUST R 225750 LIGNOCAINE HYDROCHLORIDE 5% W/V % PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION (File No: 2013/014736).

Copy of the corrected finished Drug Product Specification is attached. Please note the manufacturer has elected to state the specification in terms of 0.100g rather than 100mg :

Current **(Module 3.2.P.5.1)**	**Corrected** **(Module 3.2.P.5.1)**
Spray weight Mean of 15 measurements ± 10% of 100.0µg (90.0-110.0 µg). No individual measurement > ± 15% of 100.0µg (85.0-115.0 µg).	Spray weight Mean of 15 measurements ± 10% of 0.100g (0.090-0.110g). No individual measurement > ± 15% of 0.100g (0.085-0.115g).

Thanks and kind regards,
s22

LINKHEALTHCARE
PRETORIA SYDNEY SINGAPORE AUCKLAND TOKYO HONG KONG
s22
Senior Regulatory Affairs Associate
(T): +61 (2) 8401 9777
(F): +61 (2) 8401 9786
(E): s22 @linkhealthcare.com.au
I am in the office Mon/Tue/Thu/Fri

From: s22 @tga.gov.au]
Sent: Friday, 6 February 2015 12:43 PM
To: s22
Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

Dear s22

I have been asked to respond to your enquiry below.

The case that you have described seems straightforward, and no formal regulatory action should be needed.

If you can provide me with the details of the affected product(s), and with the corrected specification document, I will place the corrected document on file.

Let me know if this will be acceptable to you.

Regards,
s22

s22
Senior Evaluator
OTC Medicines Evaluation Section
Medicines Authorisation Branch

Phone: s22 Fax: s22
Email: s22 @tga.gov.au

Therapeutic Goods Administration
Australian Government Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @linkhealthcare.com.au]
Sent: Friday, 23 January 2015 9:24 AM
To: OTC Medicines

Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

Hi s22
Thank you for your quick reply.

The typographical error is in the units of the specification for the spray weight : µg is incorrect and should read mg. It is suspected the typo came about because the spray volume is 100µL, but the spray weight is 100mg. There is no change to the actual specification for the finished product because the spray weight has always been 100mg.

Current **(Module 3.2.P.5.1)**	**Proposed** **(Module 3.2.P.5.1)**
Spray weight Mean of 15 measurements ± 10% of 100.0µg (90.0-110.0 µg). No individual measurement > ± 15% of 100.0µg (85.0-115.0 µg).	Spray weight Mean of 15 measurements ± 10% of 100.0mg (90.0-110.0 mg). No individual measurement > ± 15% of 100.0mg (85.0-115.0 mg).

Kind regards,
s22

From: s22 @tga.gov.au] **On Behalf Of** OTC Medicines
Sent: Friday, 23 January 2015 9:14 AM
To: s22
Subject: RE: Request advice on procedure to correct an error [SEC=UNCLASSIFIED]

HI s22

Could you please advise the type of typographical error? Does it involve actual limits?

s22

OTC Medicines
Application Management & Export
Medicines Authorisation Branch
Phone: s 22
Email: otc.medicines@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22 @linkhealthcare.com.au]

Sent: Friday, 23 January 2015 9:02 AM
To: OTC Medicines
Subject: Request advice on procedure to correct an error

Dear Sir or Madam,
Please may I request advice on how to proceed to correct a typographical error in the finished product specification of an approved OTC medicine?

Kind regards,
s22

I am in the office Mon/Tue/Thu/Fri

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

4 February 2019

Re: **Application No:** OM-2018-GL-12990-1
Change Codes: **GPI, PLS**
Application level: **C2, C1**
Variation: **Section 23, Section 9D(3)**

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia v3.1
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Initial
Sequence number	0000
Related sequence	0000
Date	2019.02.04
Electronic media	Electronic via eBS portal
Submission size	~ 2 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Bioinnova Pty Ltd (EID: 68187) here with submits a variation to update the registered details for the abovementioned products.

Nature and scope of the application:
This application seeks to include change in excipient ingredient - fragrance, flavor and colouring agent in formulation and addition of pack size.

Rationale/Justification for changes:
Change is proposed to make the formulation more palatable and marketing purpose.

Proposed changes:
The following changes come under the change category:
Formulation changes - excipient ingredients

#	Change code	Change type	App level
1	**GPI**	**Removal and/or addition of a fragrance, flavour, printing ink and/or colouring agent(s) (if grouping applies), other than change ERT**	**C2**
	Proposed change/s: addition of a fragrance, flavour, printing ink and/or colouring agent.		
	Assurances: 1. The 'new' goods are intended to replace the existing goods in use. 5. No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process), have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the Changes Table. 13. 1. The changeover has been validated* and the Sponsor is satisfied that the change will not adversely affect the stability of the product; and 2. Stability testing will continue for the full term of the product's shelf life and the TGA advised immediately of any batches not meeting specifications. *Note: Validation data will be provided during a GMP inspection or upon request by the TGA within 3 months following the request (also see Guidelines on quality aspects of OTC applications		
2	**PLS**	**Addition of a pack size for liquids/semi-solids other than as described in PLN**	**C1**
	Proposed change/s: Addition of 50mL pack size.		
	Assurances: 5. No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process), have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the Changes Table. 6. The labelling for the new pack size is unchanged, other than to indicate the new pack size number/volume. 10. The container type (as defined in TGA Approved Terminology for Medicines) is unchanged and container material is unchanged. 13. 1. The changeover has been validated* and the Sponsor is satisfied that the change will not adversely affect the stability of the product; and 2. Stability testing will continue for the full term of the product's shelf life and the TGA advised immediately of any batches not meeting specifications. *Note: Validation data will be provided during a GMP inspection or upon request by the TGA within 3 months following the request (also see Guidelines on quality aspects of OTC applications		

Supporting documentation:
1.0.1 Attachment 1: Comparative current and proposed formulation

The process validation for the propsed formulation and pack size will be performed before commercialising the product with the proposed formulation and pack size. The process validation batches will be charged on stability studies and TGA will be notified immediately of any batches not meeting specifications through the shelf life.

I trust the information provided is satisfactory. However, should you wish to discuss this application please do not hesistate to contact me with the details below.

Fees:
The fees will be paid by electronic bank transfer within 14 days of submission.

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]


s47

Tracking Table

Sequence	Sequence type	Sequence description	Related sequence
0000	OTC-C2 variation	Initial	0000

Module 3: Drug Product

	Lignocaine HCl 5% w/v and Phenylephrine HCl 0.5% w/v Topical Solution

3.2.P.1 Description and Composition of the Drug Product

The drug product is a clear, colourless, sterile solution containing lignocaine hydrochloride 5% w/v and phenylephrine hydrochloride 0.5% w/v in Water for Injections for topical application.

Lignocaine hydrochloride and phenylephrine hydrochloride are established drug substances with well-characterised physicochemical properties.

The composition of the drug product is provided in the following table:

s47

From: s22
To: s22
Subject: Re: OM-2019-00126-1 S31 [SEC=UNOFFICIAL]
Date: Thursday, 13 June 2019 1:40:07 PM
Attachments: n004445.zip

Dear s22
Please find attached our response to the request received on 12 April 2019 for application OM-2019-00126-1.
Have a great day.
Kind regards,
s22

On Thu, May 2, 2019 at 10:09 AM s22 @health.gov.au> wrote:

> Dear s22
>
> Yes that's fine.
>
> Cheers
>
> s22
>
> **From:** s22 @bioinnova.com.au]
> **Sent:** Thursday, 2 May 2019 9:49 AM
> **To:** s22
> **Subject:** Re: OM-2019-00126-1 S31 [SEC=UNOFFICIAL]
>
> Dear s22
>
> Thank you for your email. We would like to request for an extension to provide the s31 response. May I please request you to provide us extension until 14 June 2019 for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORIDE 0.5% w/v TOPICAL SOLUTION (AUST R 225750)?
>
> Thank you once again.
>
> Kind regards
>
> s22
>
> On Fri, Apr 12, 2019 at 4:17 PM s22 @health.gov.au> wrote:

Dear s22

Please find attached the s31 request for this submission

Regards

s22

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Date: 13/06/2019

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Subject: Response to the Section 31 request
Submission of response to the Section 31 request received on 12 April 2019 for LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION ARTG 225750

Submission ID: OM-2019-00126-1
eSubmission identifier: n004445

Dear Sir / Madam,

Please find herewith response for S31 request received on 12 April 2019.

Format	NeeS (v.3.1)
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: (68187)
Submission number	OM-2019-00126-1
Active ingredient name	LIGNOCAINE HYDROCHLORIDE/ PHENYLEPHRINE HYDROCHLORDE
Dosage form	TOPICAL SOLUTION
Strengths	2.5mL and 50mL
Sequence type	Supplementary information
Regulatory activity lead	OTC
Sequence number	0001
Sequence description	Response to request for information – consolidated
Related sequence	0000
Date	2019-06-13
Submission size	~2 Mb
Validation	Lorenz eValidator version 18.1

This application is presented in NeeS format and has been validated using the Lorenz eValidator.

The Sponsor declares that the submission is virus free and has been checked using the antivirus software Trend Micro Worry-Free™ Business Security version 9.0. Files are provided in pdf format and have been generated using Adobe Acrobat XI Pro.

We look forward to your consideration of this application. Please do not hesitate to contact the undersigned for any further information or clarification.

Yours sincerely,

s22 [redacted]

s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019

S31 Request for Information
Submission number: OM-2019-00126-1
TGA reference: D19-5389021

S31 Request for information

(Received on 12 April 2019)

Question:1

Please provide updated PI and CMI documents that include the new excipients and pack size. The PI should be provided in the new TGA format.

Response:

Please refer the revised PI/CMI provided in **module 1.3** with recommended changes.

Question:2

Please provide module 3.2.P.7 details for the new 50 mL bottle. Given the large difference in the size of the approved bottle (2.5 mL) and the new bottle (50 mL), stability data should be provided for the new pack size.

Response:

We acknowledge agency's comment and we commit to put commercial batches on Stability.

Approved packaging for 2.5mL bottle is Type-I clear glass. For 50mL pack size we would like to propose HDPE Bottle Extrusion Blow Molded with Pump & Nozzle. Technical Drawing for packaging is enclosed as annex-I in this response.

s47

Document 8

s47

Document 8

[redacted]

AUSTRALIAN PRODUCT INFORMATION – Lignocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v (Lignocaine Hydrochloride & Phenylephrine Hydrochloride)

1 NAME OF THE MEDICINE

Lignocaine hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
For single use in one patient only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lignocaine is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of lignocaine may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of lignocaine so that patients given these drugs together may show signs of lignocaine toxicity. They should be closely observed.

Antiarrhythmic drugs - Lignocaine can have additive effects or antagonistic effects. **Suxamethonium-** Lignocaine prolongs the action of suxamethonium.

Phenytoin- Lignocaine and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lignocaine is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of lignocaine. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lignocaine hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of lignocaine and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of lignocaine and restrict bleeding. It also decreases the onset of action and increases the duration of action of lignocaine. Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this

medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

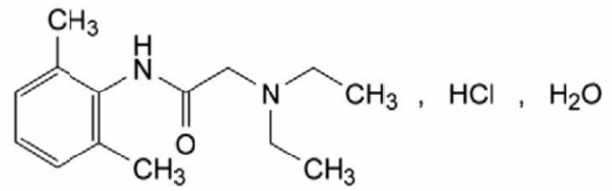
Pump actuated topical solution:
Lignocaine 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

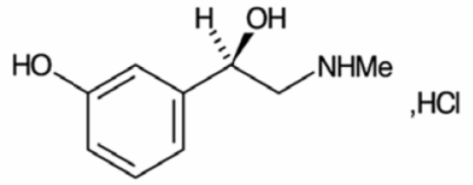
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for lignocaine hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: lignocaine hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

Luminarie Pty Ltd
Baulkham Hills
NSW 2153
Australia
http://www.luminarie.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

13 June 2019

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included

AUSTRALIAN PRODUCT INFORMATION – Lignocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v (Lignocaine Hydrochloride & Phenylephrine Hydrochloride)

1 NAME OF THE MEDICINE

Lignocaine hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
For single use in one patient only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lignocaine is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of lignocaine may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of lignocaine so that patients given these drugs together may show signs of lignocaine toxicity. They should be closely observed.

Antiarrhythmic drugs - Lignocaine can have additive effects or antagonistic effects. **Suxamethonium-** Lignocaine prolongs the action of suxamethonium.

Phenytoin- Lignocaine and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lignocaine is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of lignocaine. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lignocaine hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of lignocaine and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of lignocaine and restrict bleeding. It also decreases the onset of action and increases the duration of action of lignocaine. Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

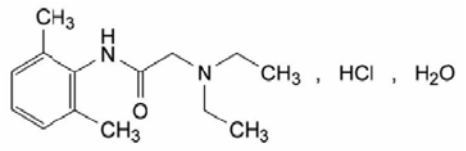
Pump actuated topical solution:
Lignocaine 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

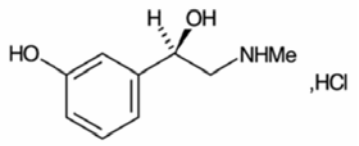
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for lignocaine hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: lignocaine hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

~~Link Medical Products PTY LTD.~~
~~5 Apollo Street~~
~~Warriewood~~
~~NSW 2102.~~

Luminarie Pty Ltd
Baulkham Hills
NSW 2153
Australia
http://www.luminarie.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

13 June 2019

Formatted: Font: Not Bold

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients lignocaine hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lignocaine hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. 2.5mL bottle should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lignocaine the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of lignocaine on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of lignocaine (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of lignocaine in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

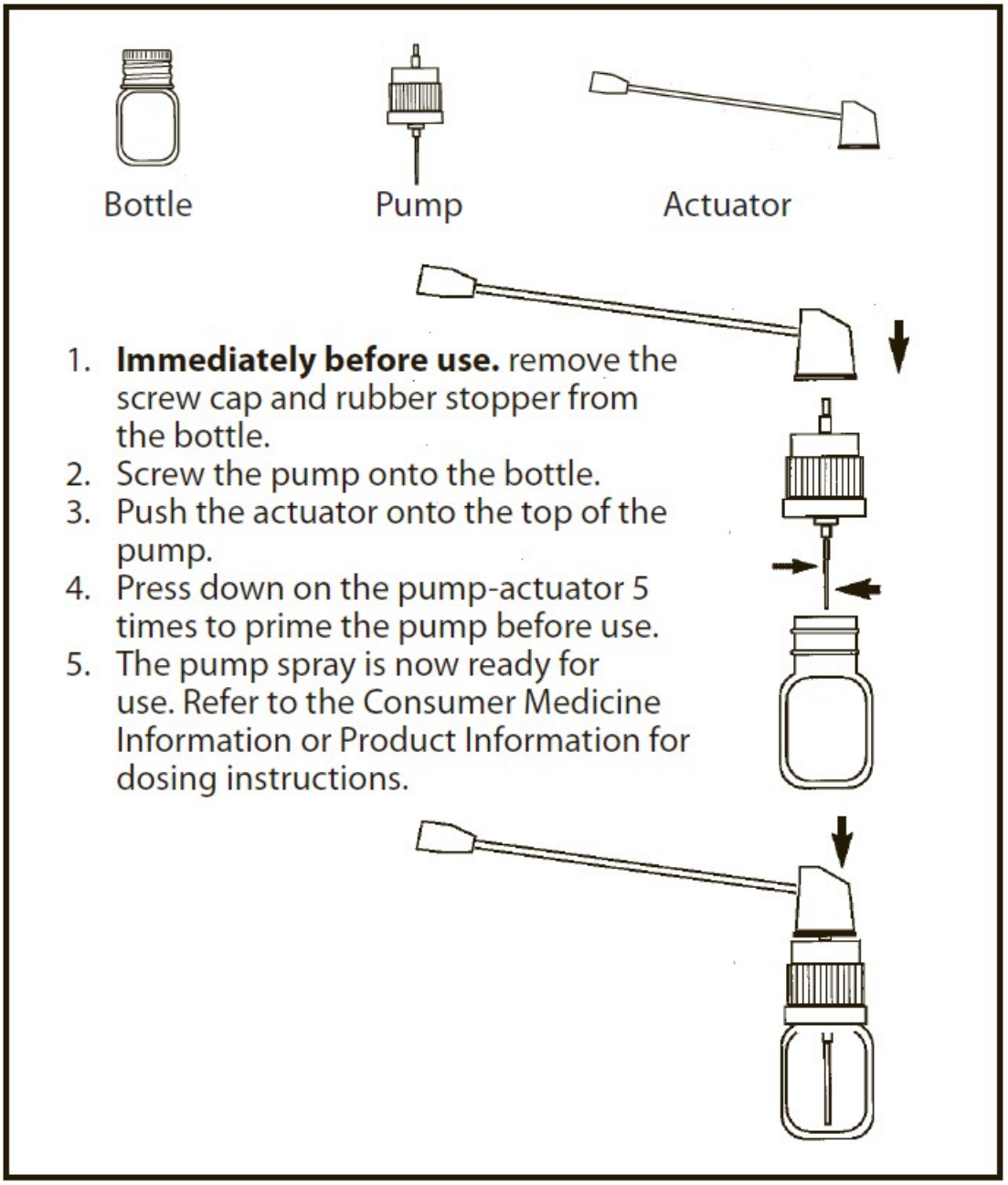
Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

Luminarie Pty Ltd
Baulkham Hills
NSW 2153
Australia
http://www.luminarie.com.au

This leaflet was prepared June 2019.

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip
The product is sterile until opened, and contains no preservative.
Use once in one patient only and discard the bottle and any remaining solution in an appropriate manner.

From: s22
To: s22 @bioinnova.com.au
Cc: COMB Systems
Subject: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]
Date: Tuesday, 18 June 2019 12:17:14 PM
Attachments: OM-2019-00126-1 s25 approval.pdf

Dear s22

Please find attached the approval letter for this submission.

Cheers
s22

Australian Government

Department of Health
Therapeutic Goods Administration

Submission ID: OM-2019-00126-1
Our reference: D19-5387827

The Managing Director
Bioinnova Pty Ltd
s22 [redacted]

Attention: s22 [redacted]
Email: s22 [redacted]@bioinnova.com.au

Dear Sir/Madam

APPLICATION UNDER s. 23 TO REGISTER A NEW MEDICINE UNDER s. 25 IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

I refer to your application under section 23 of the *Therapeutic Goods Act 1989* (the Act) dated 4 February 2019 to register

LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION

(the medicine) in the Australian Register of Therapeutic Goods (the ARTG) which, while a separate and distinct good under subsection 16(1) of the Act, is the same as registered medicine

LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION (AUST R 225750)

(the "currently registered medicine") except as follows:

- The formulation has changed &
- An additional 50 mL pack size has been included.

Decision

As delegate of the Secretary of the Department of Health, I am:

- under subsection 25(3) of the Act, approving the registration of the medicine in the ARTG on the basis that the only difference between the proposed medicine and the currently registered medicine are the changes listed above;
- under subsection 25AB(2) of the Act, notifying you of the decision to register the medicine;
- under subsections 25AA(1) of the Act, approving the text of the PI for the medicine under paragraph 25AB(3)(b) of the Act, notifying you of the approved PI as set out at **Attachment 2** &
- under subsection 28(2B) of the Act, applying conditions of registration of the medicine, as outlined under '**Conditions of Registration**' below.

Section 25, subsections 25AA(1) and (1A), section 25AB and section 28 of the Act can be found online at the following link: https://www.legislation.gov.au/Series/C2004A03952

Date of effect and supply

Under subsection 16(1) of the Act, the new medicine is a separate and distinct good. However, because you have indicated that the new medicine will replace the existing medicine, the same AUST R number may be used by reason of the Therapeutic Goods (Groups) Order No. 1 of 2001.

The date of effect of the new registration is the date specified in the Certificate of Registration, a copy of which may be obtained via the eBusiness Services (eBS) facilities shortly after receipt of the patent certification requested below. This should be the date included under the heading "date of the most recent amendment" at the end of the approved PI as set out at **Attachment 2**.

Conditions of registration

The conditions applying to the new registration of the medicine are:

1. Conditions applicable to all therapeutic goods as specified in the current edition of the document "Conditions- standard and specific: Applying to registered or listed therapeutic goods under section 28 of the *Therapeutic Goods Act 1989*", and
2. Conditions applicable to the relevant category and class of therapeutic goods as specified in the current edition of the document " Conditions- standard and specific: Applying to registered or listed therapeutic goods under section 28 of the *Therapeutic Goods Act 1989*".

Action required of you

Before the medicine can be included in the ARTG, you are required to either:

- notify the Secretary using the approved form that the patent certification under subsection 26B(1) of the Act is not required in relation to the application; or
- provide a certificate required under subsection 26B(1) of the Act.

Note:

The requirement for patent certificates does not apply to applicants for registration of medicines who are not required to submit evidence or information to establish the safety or efficacy of the goods as part of the registration process. In these circumstances, the applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the application.

The notification form and patent certificate can be downloaded via the TGA website (http://www.tga.gov.au/form/australia-united-states-free-trade-agreement). You should forward the completed and signed certificate or notification to otc.medicines@health.gov.au. A certificate of registration can only be issued after receipt of the completed and signed certificate or notification.

Review rights

Details of your review rights are at **Attachment 1**.

Your obligations in relation to Product Information

You are reminded that an approved PI for a medicine cannot be changed without the approval of the Secretary under subsection 25AA(4) of the Act.

You are also reminded that the CMI must comply with the requirements set out in the Therapeutic Goods Regulations 1990 which includes the obligation to ensure the CMI that must be supplied with the medicine is 'consistent with' the approved PI.

Other matters

A copy of the final consumer medicine information is provided at **Attachment 3**.

You are reminded of the pharmacovigilance reporting requirements as set out in the document "*Pharmacovigilance responsibilities of medicine sponsors – Australian recommendations and requirements*", including the requirement to keep the Australian pharmacovigilance contact person details up to date through the TGA Business Services electronic portal.

Please note that it is your responsibility to ensure that current Good Manufacturing Practice clearance letters are maintained for all overseas sites of manufacture registered for the products.

Please do not hesitate to contact me if you have any further queries regarding this matter.

Yours faithfully

Signed and authorised by
s22
Delegate of the Secretary
Complementary & OTC Medicines Branch
Email: s22 @health.gov.au

18 June 2019

Attachments:

1. Review rights
2. A copy of approved product information
3. A copy of final consumer medicine information

Attachment 1

Request for reconsideration of an initial decision

The decisions under sections 25 and 28 of the Act are 'initial decisions' within the meaning of section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted. The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and '**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Attachment 2 – PI

AUSTRALIAN PRODUCT INFORMATION – Lignocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v (Lignocaine Hydrochloride & Phenylephrine Hydrochloride)

1 NAME OF THE MEDICINE

Lignocaine hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
For single use in one patient only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lignocaine is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of lignocaine may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of lignocaine so that patients given these drugs together may show signs of lignocaine toxicity. They should be closely observed.

Antiarrhythmic drugs - Lignocaine can have additive effects or antagonistic effects. **Suxamethonium**- Lignocaine prolongs the action of suxamethonium.

Phenytoin- Lignocaine and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2**- Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lignocaine is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of lignocaine. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lignocaine hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of lignocaine and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of lignocaine and restrict bleeding. It also decreases the onset of action and increases the duration of action of lignocaine. Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this

medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

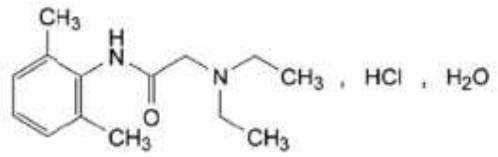
Pump actuated topical solution:
Lignocaine 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

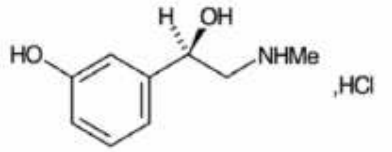
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for lignocaine hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: lignocaine hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

Luminarie Pty Ltd
Baulkham Hills
NSW 2153
Australia
http://www.luminarie.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

13 June 2019

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included

Attachment 3 – CMI

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients lignocaine hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lignocaine hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. 2.5mL bottle should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lignocaine the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of lignocaine on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of lignocaine (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of lignocaine in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

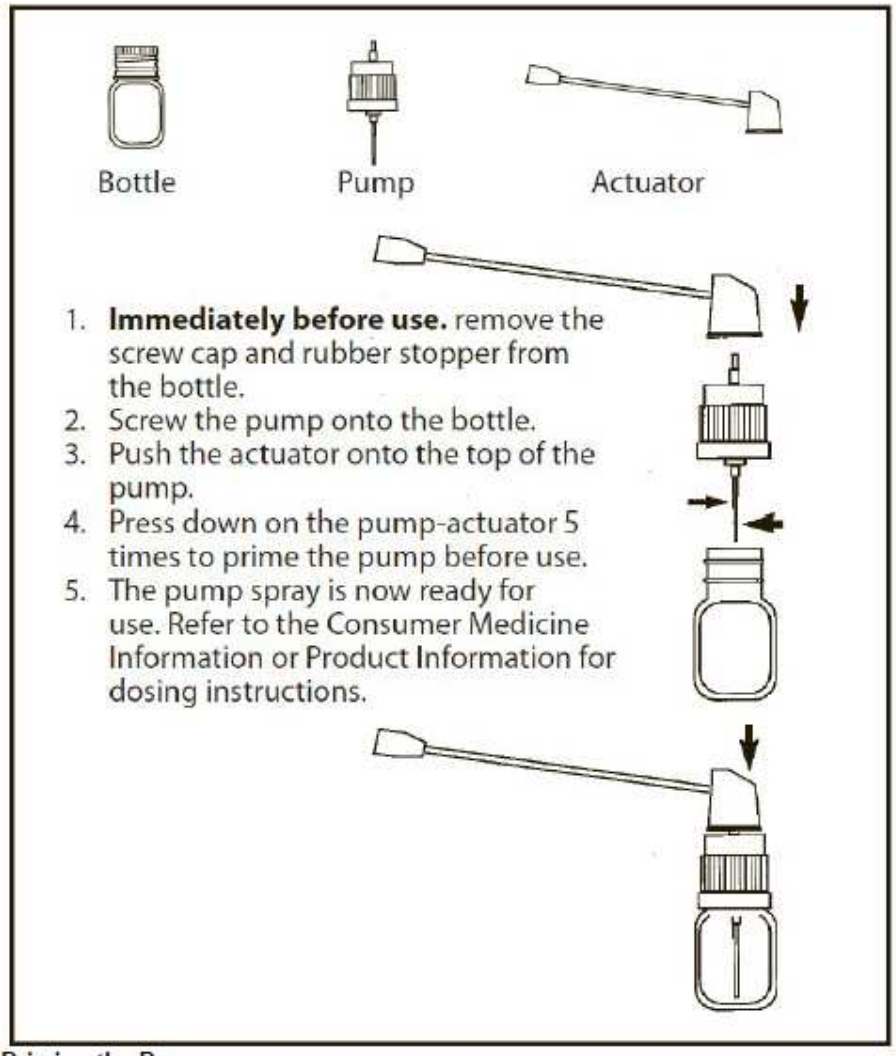
Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

Luminarie Pty Ltd
Baulkham Hills
NSW 2153
Australia
http://www.luminarie.com.au

This leaflet was prepared June 2019.

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip
The product is sterile until opened, and contains no preservative.
Use once in one patient only and discard the bottle and any remaining solution in an appropriate manner.

From: s22
To: s22
Subject: Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]
Date: Wednesday, 31 July 2019 11:47:51 AM

Thank you, s22
I have accepted the changes.

Thanks
s22

On Wed, Jul 24, 2019 at 12:51 PM s22 @health.gov.au> wrote:

> G'day s22
>
> Have a look – when it become available to validate – and see how I did it. I didn't specify the container material and included this information in the additional info.
>
> If you're happy with that then validate it.
>
> Cheers
>
> s22
>
> **From:** s22 @bioinnova.com.au]
> **Sent:** Wednesday, 24 July 2019 12:38 PM
> **To:** s22
> **Subject:** Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]
>
> Hi s22
>
> Thank you for your feedback.if necessary, we can remove the glass and include HDPE.
>
> s47
>
> Please let me know if it's possible.
>
> Regards,
>
> s22
>
> On Wed, Jul 24, 2019 at 12:17 PM s22 @health.gov.au>

wrote:

> It's difficult with both containers under the same ARTG number (they probably shouldn't be).
>
> s47 [redacted]
>
> See what you think and if you're happy then sponsor validate it and let me know.
>
> Cheers
>
> s22 [redacted]
>
> **From:** s22 [redacted] @bioinnova.com.au]
> **Sent:** Monday, 22 July 2019 9:58 AM
> **To:** s22 [redacted]
> **Subject:** Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]
>
> Dear s22 [redacted]
>
> Apologies for the delay. s47 [redacted] however for 50mL we will using HDPE. Could you please update this?
>
> Regards,
>
> s22 [redacted]
>
> On Mon, Jul 15, 2019 at 4:10 PM s22 [redacted] @health.gov.au> wrote:
>
> > Dear s22 [redacted]
> >
> > I've made the changes to the PARs, if you can now 'sponsor verify' them – by following the instructions below – and letting me know when you've done it that would be great.
> >
> > Cheers

s22

To verify the application details:

1. Click on the "View submissions" link on the TGA Business Services homepage.

2. Click the 'down arrow' on the left hand side of the product listing, then click "Print Preview". This will show the original application and TGA revised application on the same screen.

3. After reviewing, click "Continue" (top left, under "I agree with the changes:"). This will open the Declaration page. Click "Agree"

From: s22 @bioinnova.com.au]
Sent: Monday, 15 July 2019 1:34 PM
To: s22
Subject: Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]

Dear s22

Pepperment water is listed in TGA's register now. ID is 123049.

Could you please validate the record and include 50mL packing and HDPE container?

Thank you.

Kind regards,

s22

On Tue, Jun 25, 2019 at 10:20 AM s22
<s22 @health.gov.au> wrote:

> Dear s22
>
> I think that will be OK. Let me know when you have the concentrated peppermint registered, then I will change the PARs and get you to do a sponsor verification.

Cheers

s22

From: s22 @bioinnova.com.au]
Sent: Tuesday, 25 June 2019 10:00 AM
To: s22
Subject: Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]

Dear s22

Thank you for your advice. I will request TGA to include 'Concentrated Peppermint Water' if it isn't registered.

For containers, s47 we wish to keep 50mL pack size with HDPE bottle.

Please advise.

Thank you.

Kind regards,

s22

On Mon, Jun 24, 2019 at 11:42 AM s22 s22 @health.gov.au> wrote:

> Dear s22
>
> As far as I can understand it, you can't have a vial and a bottle under the same ARTG entry – the bottle would become a separate and distinct good.
>
> We can get around this problem by calling the 2.5 mL and 50 mL presentations both bottles. Is this suitable?
>
> The other problem is that the PARs aren't validating because the flavouring ingredient 'Concentrated Peppermint Water' isn't a registered PI – at least according to the ARTG. I think that's a problem you'll need to fix by getting the ingredient

registered.

Cheers

s22

From: s22 @bioinnova.com.au]
Sent: Friday, 21 June 2019 4:20 PM
To: s22
Subject: Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]

Dear s22

Thank you for your prompt response. From the approval letter, I understood that we got approval for additional flavor ingredients, 50mL pack size, and container HDPE for 50mL. Could you please advise if my understanding is correct?

Kind regards,

s22

On Fri, Jun 21, 2019 at 4:01 PM s22 <s22 @health.gov.au> wrote:

> It looks OK apart from the fact the HDPE hasn't been included for the 50 ml bottle size and I'm not quite sure how to deal with that.
>
> **From:** s22 @bioinnova.com.au]
> **Sent:** Friday, 21 June 2019 3:43 PM
> **To:** s22
> **Subject:** Re: OM-2019-00126-1 s25 approval [SEC=UNOFFICIAL]
>
> Dear s22
>
> Thank you for considering our application and approval. However, new pack size, flavour and container type HDPE bottle is not been updated in ARTG records. Could you please advise if any action required from our side.
>
> Kind regards,
>
> s22

On Tue, Jun 18, 2019 at 12:17 PM [redacted] <[redacted]@health.gov.au> wrote:

Dear [redacted]

Please find attached the approval letter for this submission.

Cheers

[redacted]

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

8 September 2019

Re: **Application No:** **OM-2019-GL-07903-1**
Change Codes: **GPN, LCF, LFT, LIR, LNT, LSP, LGR**
Application level: **CN, C1, C2**
Variation: **Section 23,9D(2C), 9D(3)**

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Initial
Sequence number	0002
Related sequence	0002
Date	2019.09.04
Electronic media	Electronic via eBS portal
Submission size	~ 2 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Bioinnova Pty Ltd (EID: 68187) here with submits a variation to update the registered details for the abovementioned products.

Nature and scope of the application:
This application seeks to change the trade names and Change in labels as specified below. We wish to retain the same ARTG number for the proposed trade name.

From “LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION” to “LidoPhenyl Spray”

Proposed changes:
The following changes come under the change category:
Labelling (including package insert) and product detail changes

#	Change code	Change type	App level
1	**LSP**	Changes to sponsor details including name and/or logo (inclusion of a logo or change to an existing logo) except where LAB applies	*CN*
	LFT	Font or type size other than change to the type size on the main panel of the label. Does not include change in colour or label copy.	*CN*
	LCF	Colour or type size change (no change in label copy), other than where LFT applies	*C1*
	GPN	Proprietary name (if grouping applies) where: 1. the product name does not include an umbrella branded name or 2. if it does contain an umbrella branded name , then the umbrella segment is not categorised as requiring a higher level of assessment	*C2*
	LNT	Changes to bring a label into full compliance with Therapeutic Goods Order No. 92 - other than changes to the proprietary name. If changing proprietary name (and where grouping applies), also use code GPN or GPU	*C2*
	LGR	Introduction of new graphics/icons (other than as specified in change LSP & KSP)	*C2*
	LIR	Therapeutic indications - addition of registered indications to label	*C2*
	Proposed change/s: Change in Tradename, Change in sponsor details, Change in labels according to new sponsor's designs and bring a labels in compliance with TGO 92.		
	Assurances: 1. The "new" goods are intended to replace the existing goods in use. 5. No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process), have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the Changes Table. 7. The only changes made are those which bring the label into compliance with the requirements of the labelling Order, or Schedule 2 to the Therapeutic Goods Regulations 1990.		

Supporting documentation:
Module 1 Product Information, CMI and Proposed labels

Fees:
The fees will be paid by electronic bank transfer within 14 days of submission.

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lignocaine hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
For single use in one patient only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lignocaine is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of lignocaine may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of lignocaine so that patients given these drugs together may show signs of lignocaine toxicity. They should be closely observed.

Antiarrhythmic drugs - Lignocaine can have additive effects or antagonistic effects. **Suxamethonium-** Lignocaine prolongs the action of suxamethonium.

Phenytoin- Lignocaine and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lignocaine is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of lignocaine. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lignocaine hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of lignocaine and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of lignocaine and restrict bleeding. It also decreases the onset of action and increases the duration of action of lignocaine. Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

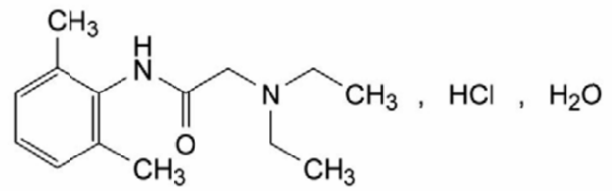
Pump actuated topical solution:
Lignocaine 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

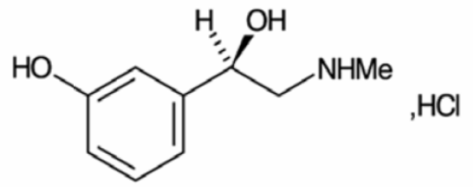
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for lignocaine hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: lignocaine hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray ~~Lignocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v (Lignocaine Hydrochloride & Phenylephrine Hydrochloride)~~

1 NAME OF THE MEDICINE

Lignocaine hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
For single use in one patient only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lignocaine is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of lignocaine may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of lignocaine so that patients given these drugs together may show signs of lignocaine toxicity. They should be closely observed.

Antiarrhythmic drugs - Lignocaine can have additive effects or antagonistic effects. **Suxamethonium-** Lignocaine prolongs the action of suxamethonium.

Phenytoin- Lignocaine and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lignocaine is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of lignocaine. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lignocaine hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of lignocaine and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of lignocaine and restrict bleeding. It also decreases the onset of action and increases the duration of action of lignocaine. Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

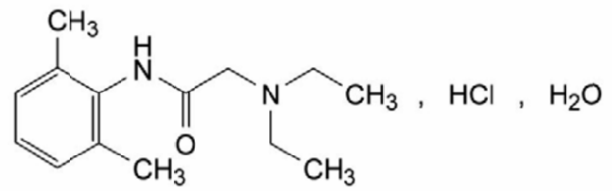
Pump actuated topical solution:
Lignocaine 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

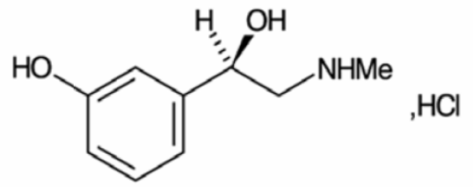
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for lignocaine hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: lignocaine hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

~~Luminarie Pty Ltd~~
~~Baulkham Hills~~
~~NSW 2153~~
~~Australia~~
~~http://www.luminarie.com.au~~
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

~~13 June 2019~~ XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed

LidoPhenyl Spray (Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v)

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients lignocaine hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lignocaine hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lignocaine the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of lignocaine on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of lignocaine (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of lignocaine in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

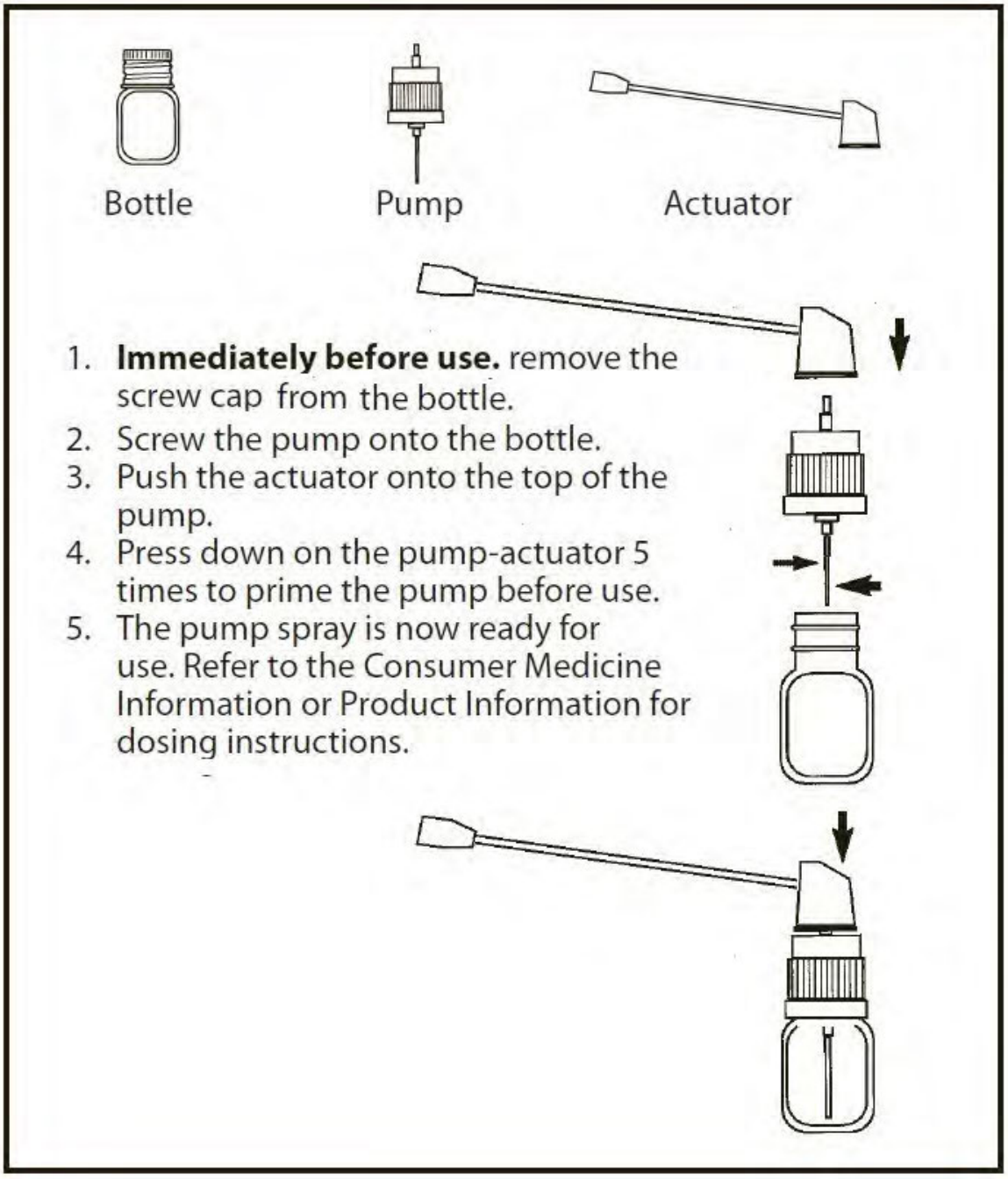
Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

This leaflet was prepared September 2019.

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip
The product is sterile until opened, and contains no preservative.
Use once in one patient only and discard the bottle and any remaining solution in an appropriate manner.

LidoPhenyl Spray (Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v) ~~Topical Solution~~

Formatted: Font: (Default) Arial Black, (Intl) Arial, English (United States), Check spelling and grammar

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients lignocaine hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lignocaine hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lignocaine the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of lignocaine on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of lignocaine (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of lignocaine in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

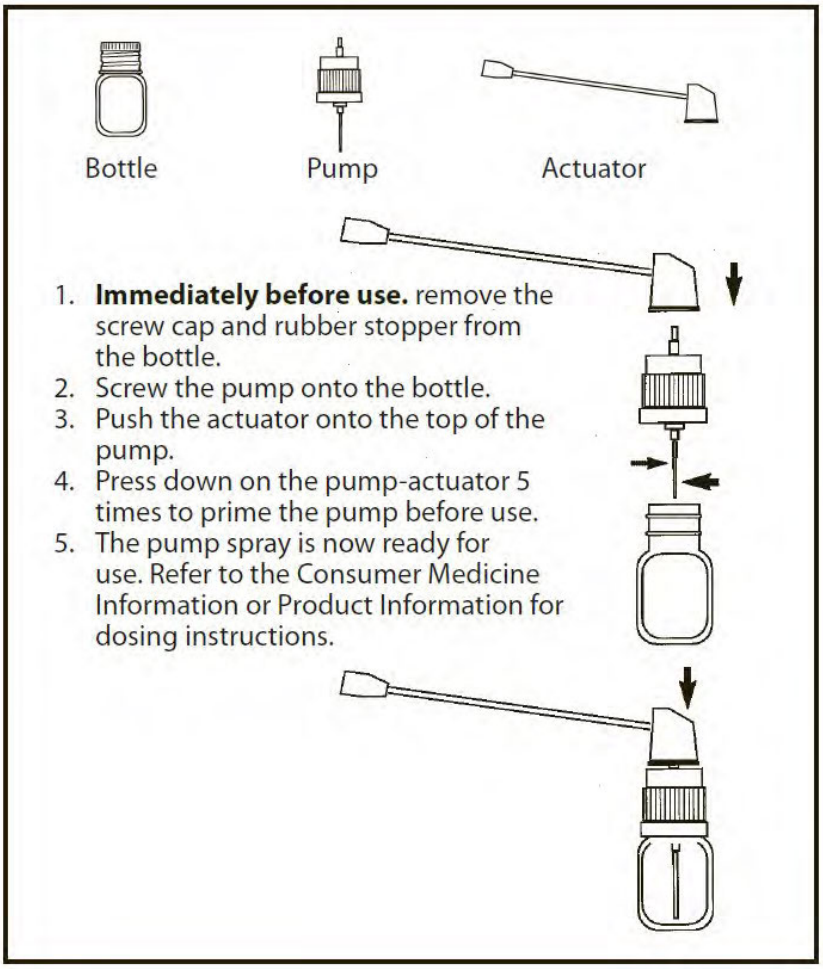
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au
~~Luminario Pty Ltd~~
~~Baulkham Hills~~
~~NSW 2153~~
~~Australia~~
~~http://www.luminario.com.au~~

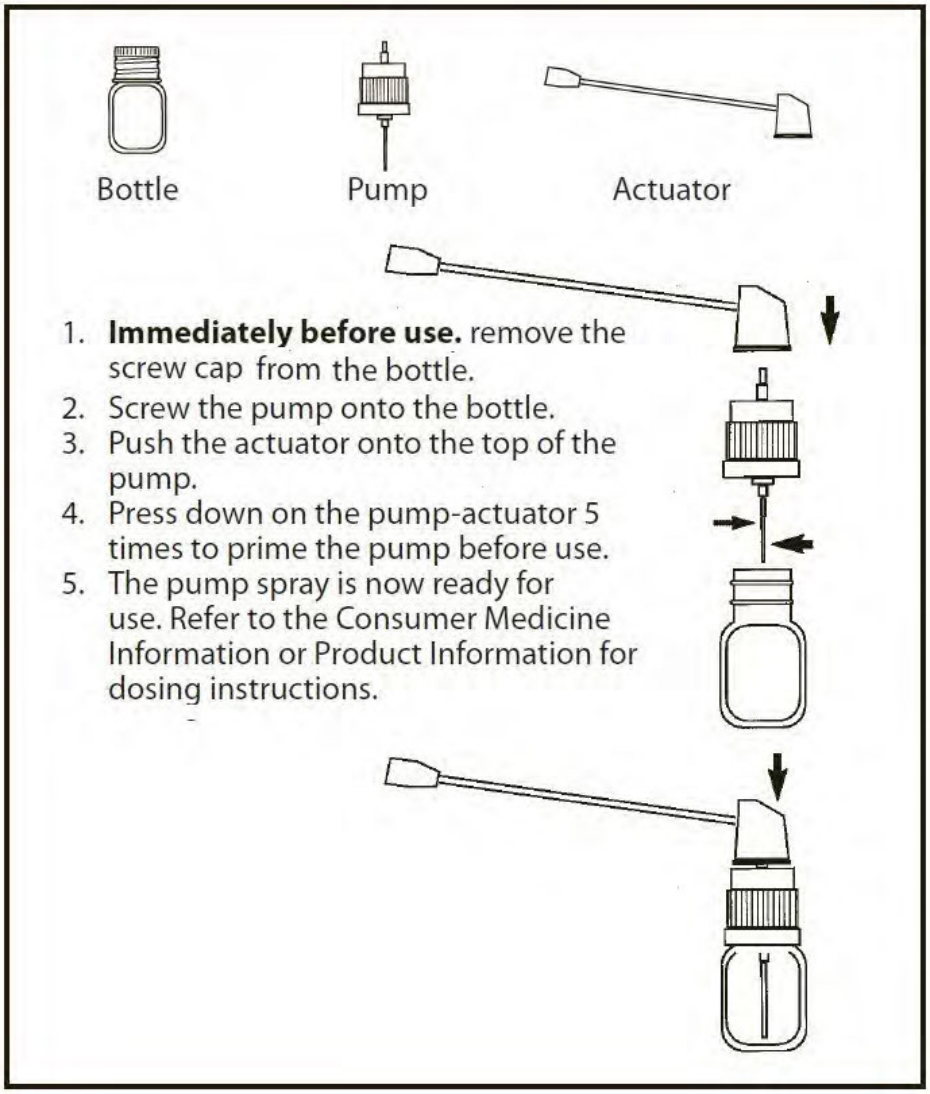
This leaflet was prepared ~~June~~ September 2019.

Formatted: Indent: Left: 0.25 cm

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle

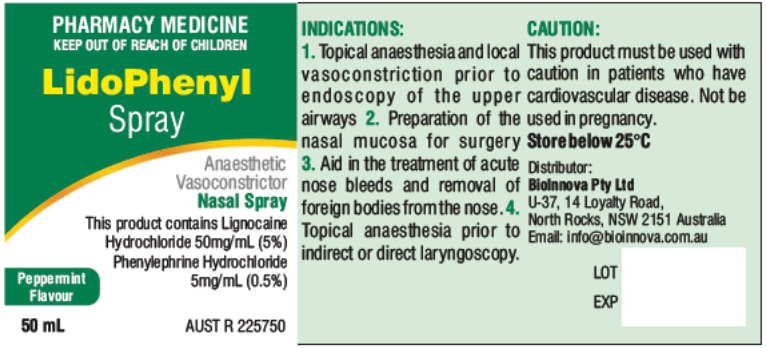




Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip
The product is sterile until opened, and contains no preservative.
Use once in one patient only and discard the bottle and any remaining solution in an appropriate manner.



100 mm x 45 mm

s47

Size: 100 mm x 45 mm

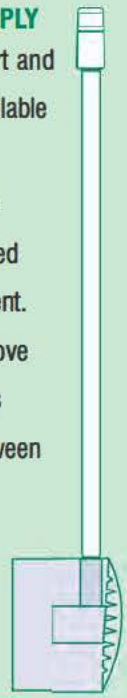
PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

NOZZLE SUPPLY

Nozzles (short and long) are available separately.

A new nozzle should be used for each patient. This will remove risks of cross infection between patients.



DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

MEDICINE INFORMATION:
ACTIVE INGREDIENT:
Lignocaine Hydrochloride 50mg/mL (5%) and Phenylephrine Hydrochloride 5mg/mL (0.5%)

USES:
1. Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper airways
2. Preparation of the nasal mucosa for surgery
3. Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
4. Topical anaesthesia prior to indirect or direct laryngoscopy.

WARNINGS:
These doses are to be administered once only. They may be repeated as directed only by a physician.

This product must be used with caution in patients who have cardiovascular disease. Not be used in Pregnancy.

9 349777 008637

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl Spray

Anaesthetic Vasoconstrictor **Nasal Spray**

Peppermint Flavour

This product contains
Lignocaine Hydrochloride 50mg/mL (5%)
Phenylephrine Hydrochloride 5mg/mL (0.5%)

50 mL AUST R 225750

MEDICINE INFORMATION (CONTINUED):
DIRECTIONS FOR USE:
Each squirt contains 100 microlitres.

DOSAGE: Not for use in children under the age of 2 years. Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

Store below 25°C

Distributor:
BioInnova Pty. Ltd.
U-37, 14 Loyalty Road,
North Rocks, NSW 2151 Australia
Email: info@bioinnova.com.au

s47

Size: 113 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT

From: s22
To: s22
Subject: Re: OM-2019-01125-1 LidoPhenyl; Screening query [SEC=OFFICIAL]
Date: Monday, 23 September 2019 12:08:27 PM
Attachments: image001.png
carton-annotated.pdf
label-annotated.pdf
tabulated summary - proposed label.pdf

Dear s22
Thank you for your email.
Please find attached requested documents.
Please let me know if any further information is required to complete the application.

Kind regards,
s22

On Wed, Sep 18, 2019 at 2:07 PM s22
<s22 @health.gov.au> wrote:

> Dear s22
>
> **RE: OM-2019-01125-1 LidoPhenyl outcome of screening – minor omissions (C2 application)**
>
> I refer to your application seeking approval to change LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHOLORIDE 0.5% w/v TOPICAL SOLUTION (Submission ID OM-2019-01125-1, file 2013/014736).
>
> Your application and the supporting information in the application dossier have been screened to verify that it meets the requirements for applications made under section 23 of the Act to register an OTC medicine.
>
> Applications that do not meet the requirements will not be accepted for evaluation. However, where there are minor deficiencies or omissions, the applicant is given five working days to remedy the application.
>
> Your application has been identified as missing some required information that should be readily available. In order to rectify the deficiency, please provide the following information within five working days **(Due date**: **23/09/19)**.
>
> Please provide your response by email to s22 @health.gov.au.

If these omissions are not rectified before the due date, the application cannot be accepted for evaluation and will be removed from the application lodgement system in TGA eBusiness Services. Application fees cannot be refunded.

For further information on the application process and the requirements for an effective application, please refer to:

ARGOM

OTC new medicines registration process / Process to change a registered OTC medicine

General dossier requirements

Common Technical Document Module 1: OTC medicines

Mandatory requirements for an effective over-the-counter medicines application

MATTERS TO BE ADDRESSED

1. Where the proposed labelling is based on an existing label, a copy of current label with changes marked by annotations is required. Please provide a copy of the current labelling for this product.

2. Where multiple changes are proposed, a table comparing current vs proposed labels should be provided. Please provide a table with the required information.

Please contact me if you require further clarification of these matters.

Kind regards,

s22 [redacted]

Evaluator – Medicines Evaluation (OTC)

Medicines Regulation Division | Health Products Regulation Group

Complementary & OTC Medicines Branch

Australian Government Department of Health

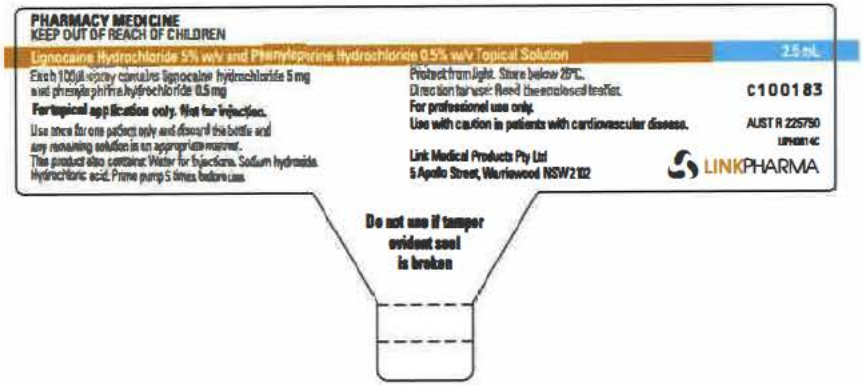
T: s22 | E: s22 @health.gov.au

Location: Therapeutic Goods Administration

PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

[redacted] s22



← 100mm MEASUREMENT VERIFICATION BAR →

MARTINDALE PHARMA

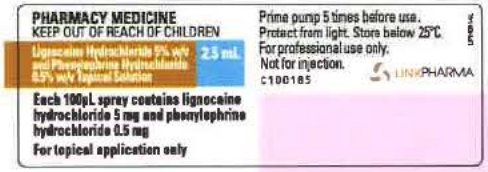
ORACLE code: **C100183**
Description: LBL Lignocaine LINK box front
Market: AUS
PCI: 0605
Replaces code: N/A
Template/style number: as supplied
Colours: PMS Black C
PMS 305 C
PMS 139 C
PMS 423 C
Min Point size (legal text): 4.58pt
Version number: **01** Date: 18/11/14 By: AC
Date of previous revision: 29/09/14 (LIPH0712C-D)
EAN Barcode: N/A

Artwork Dept
To confirm that all artwork checks have been completed prior to circulation
Name:
Signature:
Date:
Comments:

Regulatory Affairs / ~~OL customer~~ LINK HEALTHCARE
Accept ✓ ☑ Reject ✗ ☐
Name: s22 [redacted]
Signature:
Date: 28/11/14
Comments:

Quality
Accept ✓ ☐ Reject ✗ ☐
Name:
Signature:
Date:
Comments:

s47 [redacted]



← 100mm MEASUREMENT VERIFICATION BAR →

MARTINDALE PHARMA

Document 12

ORACLE code: **C100185**

Description: LBL Lignocaine LINK Vial

Market: AUS

PCI: 0605

Replaces code: N/A

Template/style number: as supplied (22 x 63.5mm)

Colours: PMS Black C
PMS 305 C
PMS 139 C
PMS 423 C

Min Point size (legal text): pt

Version number: **01** Date: 10/11/14 By: AC

Date of previous revision: 30/09/14 (LIPH0914L-D)

EAN Barcode: N/A

Artwork Dept

To confirm that all artwork checks have been completed prior to circulation

Name:

Signature:

Date:

Comments:

Regulatory Affairs ~~/OL customer~~ LINK HEALTHCARE

Accept ✓ ☑ Reject ✗ ☐

Name: s22 [redacted]

Signature:

Date: 28 Nov 14.

Comments:

Quality

Accept ✓ ☐ Reject ✗ ☐

Name:

Signature:

Date:

Comments:

s47 [redacted]

Approved label	Proposed label
Sponsor-Link Pharma	Sponsor-Bioinnova Pty Ltd
	Overall design, colour, new logo change as per new sponsors requirement
Labels for 2.5mL	50mL label
Labels as per TGO 69	Label updated as per TGO 92
No indication on label	Approved indication on label
No flavour	Addition of flavour variation approved and accordingly included peppermint flavour on label
Nozzle information in leaflet	All the information mentioned on the carton label so package leaflet will not be included in Carton.

From: s22
To: s22
Subject: Re: OM-2019-01125-1 LidoPhenyl; Clarification Required [SEC=OFFICIAL]
Date: Tuesday, 8 October 2019 11:29:59 AM
Attachments: image001.png
20141124 Ligocaine leaflet - signed.pdf

Dear s22
Good morning!
We confirm that we will not include the Package leaflet in Carton.
Please advise if we need to take any action.
Also, please find attached the current Package leaflet.

Kind regards,
s22
BioInnova Pty Ltd
s22

On Wed, Oct 2, 2019 at 10:22 AM s22
<s22 @health.gov.au> wrote:

> Dear s22
>
> **RE: OM-2019-01125-1 LidoPhenyl (C2 application)**
>
> I refer to your application seeking approval to change LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHOLORIDE 0.5% w/v TOPICAL SOLUTION (Submission ID OM-2019-01125-1, file 2013/014736).
>
> In your screening query response dated 23 September 2019, you included a tabulated summary of the proposed changes. The table included the following proposed change:
>
> | Approved label | Proposed label |
> |---|---|
> | Nozzle information in leaflet | All the information mentioned on the carton label so package leaflet will not be included in Carton. |
>
> I would like to clarify whether or not the sponsor is proposing deletion of the package leaflet?
>
> If deletion of the package leaflet is requested then the application will need to be amended to include the change code 'KRI' under section 9D(3) of the Therapeutic Goods Act 1989 and the sponsor will need to provide a copy of the current package leaflet.
>
> Please provide your response within **five working days (9 October 2019)** to s22 @health.gov.au . The clock will be stopped pending your response.

Kind regards,

s22

Evaluator – Medicines Evaluation (OTC)

Medicines Regulation Division | Health Products Regulation Group

Complementary & OTC Medicines Branch

Australian Government Department of Health

T: s22 | E: s22 @health.gov.au

Location: Therapeutic Goods Administration

PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 @bioinnova.com.au>
Sent: Monday, 23 September 2019 12:08 PM
To: s22 @health.gov.au>
Subject: Re: OM-2019-01125-1 LidoPhenyl; Screening query [SEC=OFFICIAL]

Dear s22

Thank you for your email.

Please find attached requested documents.

Please let me know if any further information is required to complete the application.

Kind regards,

s22

On Wed, Sep 18, 2019 at 2:07 PM s22

s22 @health.gov.au> wrote:

Dear s22

RE: OM-2019-01125-1 LidoPhenyl outcome of screening – minor omissions (C2 application)

I refer to your application seeking approval to change LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHOLORIDE 0.5% w/v TOPICAL SOLUTION (Submission ID OM-2019-01125-1, file 2013/014736).

Your application and the supporting information in the application dossier have been screened to verify that it meets the requirements for applications made under section 23 of the Act to register an OTC medicine.

Applications that do not meet the requirements will not be accepted for evaluation. However, where there are minor deficiencies or omissions, the applicant is given five working days to remedy the application.

Your application has been identified as missing some required information that should be readily available. In order to rectify the deficiency, please provide the following information within five working days **(Due date**: **23/09/19)**.

Please provide your response by email to s22 @health.gov.au.

If these omissions are not rectified before the due date, the application cannot be accepted for evaluation and will be removed from the application lodgement system in TGA eBusiness Services. Application fees cannot be refunded.

For further information on the application process and the requirements for an effective application, please refer to:

ARGOM

OTC new medicines registration process / Process to change a registered OTC medicine

General dossier requirements

Common Technical Document Module 1: OTC medicines

Mandatory requirements for an effective over-the-counter medicines application

MATTERS TO BE ADDRESSED

1. Where the proposed labelling is based on an existing label, a copy of current label with changes marked by annotations is required. Please provide a copy of the current labelling for this product.

2. Where multiple changes are proposed, a table comparing current vs proposed labels should be provided. Please provide a table with the required information.

Please contact me if you require further clarification of these matters.

Kind regards,

s22 [redacted]

Evaluator – Medicines Evaluation (OTC)

Medicines Regulation Division | Health Products Regulation Group

Complementary & OTC Medicines Branch

Australian Government Department of Health

T: s22 [redacted] | E: s22 [redacted]@health.gov.au

Location: Therapeutic Goods Administration

PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

> "Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

PATIENT INFORMATION SHEET C100191

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution

What is in this medication and what it is used for

This solution contains two active ingredients lignocaine hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lignocaine hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lignocaine hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. It should be used only once in one patient only and any residue discarded.

The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lignocaine the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)
- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of lignocaine on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of lignocaine (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

Continued overleaf

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages: Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of lignocaine in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:
Link Medical Products Pty Ltd
5 Apollo Street, Warriewood NSW 2102

This leaflet was prepared May 2014

C100191

MARTINDALE PHARMA	
ORACLE code: **C100191**	
Description: PIL LIGNOCAINE LINK	
Market: AUS	
PCI: 0605	
Replaces code: N/A	
Template/style number: 450 x 88mm	
Colours: PMS Black ■	PMS ☐
PMS ☐	PMS ☐
Min Point size (legal text): 8pt	
Version number: **01** Date: 21/11/14 By: AC	
Date of previous revision: 20/05/14 (D02887-A)	
EAN Barcode (if applicable):	
Artwork Dept	
To confirm that all artwork checks have been completed	
prior to circulation	
Name:	
Signature:	
Date:	
Comments:	
Regulatory Affairs / OL customer	
Accept ✓	
Name: s22 [redacted]	
Signature:	
Date: 24Nov14	
Comments:	
Quality	
Accept ✓ Reject ✗	
Name:	
Signature:	
Date:	
Comments:	

s47 [redacted]

INFORMATION FOR THE HEALTH PROFESSIONAL C100191

Lignocaine Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution

Instructions for Assembly of Pump and Actuator to Bottle

Priming the Pump.

While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage

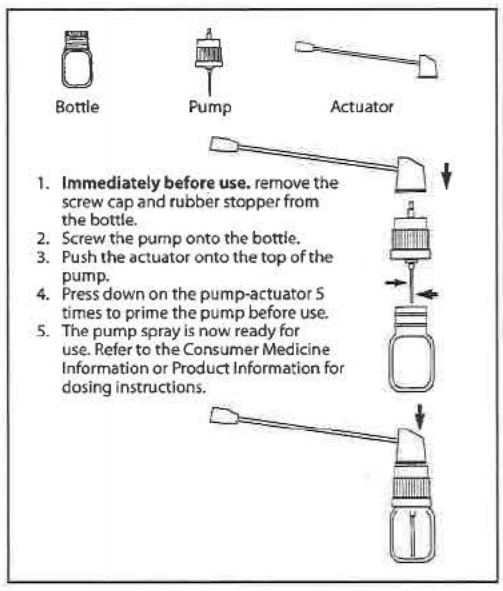
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information

Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip.
The product is sterile until opened, and contains no preservative. Use once in one patient only and discard the bottle and any remaining solution in an appropriate manner.

Continued overleaf

User Guide



C100191

100mm Measurement Verification Bar

2837-A

From: s22
To: s22
Subject: FW: OM-2019-01125-1 LIDOPHENYL; RFI for C2 Application [SEC=OFFICIAL]
Date: Monday, 25 November 2019 10:33:58 AM
Attachments: image001.png

Hey s22

I think this application was reallocated to you. s22 called me and had some questions last week. I got her to send them in writing so I could forward them to you.

Let me know if you have any questions about her questions ☺

Hope you're well btw!

Thanks
s22

From: s22 @bioinnova.com.au>
Sent: Thursday, 21 November 2019 11:38 AM
To: s22 @health.gov.au>
Subject: Re: OM-2019-01125-1 LIDOPHENYL; RFI for C2 Application [SEC=OFFICIAL]

Dear s22

We are working on the revising labels as per your below email However, we would like to inform on the below queries. Our earlier registered formulation was 2.5ml bottle and hence it was a single dose so it was recommended to discard after use. Now we have 50mL pack the same as an innovator and it is not a single dose. Hence it is recommended to use new nozzle for each patient.
We request you to please allow us to keep the below information on the proposed label.

11. As detailed in the product information document, this medicine 'should be used once in one patient only and any residue discarded'. As such, deletion of the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients' is not appropriate since it is inconsistent with the proper use of this medicine.

Please amend the labelling to include the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' in the CHI under the heading 'Warnings'.

Please delete the information 'They may be repeated as directed only by a physician' and

'A new nozzle should be used for each patient. This will remove risks of cross infection between patients.' from the product labelling.

Kind regards,

s22 [redacted]

BioInnova Pty Ltd

s22 [redacted]

On Thu, Nov 7, 2019 at 2:38 PM s22 [redacted] @health.gov.au> wrote:

> Dear s22 [redacted]
>
> **RE: OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736)**
>
> I refer to your application for a grouped change in proprietary name from LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION to LidoPhenyl (Submission ID OM-2019-01125-1, file 2013/014736).
>
> Initial evaluation of this application is now complete and I wish to advise that the following matters need to be addressed before this application is finalised:
>
> *Product Name*
>
> 1. The proposed name 'LidoPhenyl' is acceptable. However, for consistency with ARTG naming conventions the product name will be amended to 'LIDOPHENYL spray bottle'. Please log-in to eBS to verify the product name.
>
> *Labelling*
>
> 2. As per TGO 92, the product name and active ingredient information should appear as a cohesive unit on the main label and must not be interrupted by information. The proposed main label is not acceptable as it includes the text

‘Anaesthetic Vasoconstrictor Nasal Spray’ and a large face graphic between the product name and the active ingredient information. Please amend the main label for the carton and bottle labelling so the product name and active ingredients appear as a cohesive unit.

3. As per TGO 92, the quantity of the active ingredient for a metered dose product is the quantity delivered per actuation. Please amend the unit presentation of the active ingredients strengths from mg/mL to mg/actuation on the carton (including in the CHI) and bottle labelling.

4. As per TGO 92, for a non-pressurised metered dose preparation, the quantity of the medicine is the minimum number of deliverable doses in the container. Please amend the presentation of the medicine quantity from the volume in mL to the minimum number of deliverable doses, e.g. no. of sprays.

5. On the proposed carton label under the heading ‘Directions for use’, the subheading ‘dosage’ has the same formatting as the required CHI headings. The presentation of the subheading ‘dosage’ should be amended so it can be differentiated from the required CHI headings.

6. As per TGO 92, the CHI should be presented in one dark coloured text on a white or light background. Furthermore, as per the TGO 91 and TGO 92 medicine labels guidance document, colours and bold font should not be used to highlight information in the CHI. Under the sub-heading ‘Dosage’ in the dosing table, the age groups appear in bold green text and the dosing table borders appear in a light orange colour. For compliance with TGO 92, please amend the dosing table so the text appears in black non-bolded font and amend the colour of the dosing table borders to black.

7. The storage information and distributor information in the CHI appear under the heading ‘Directions for use’. For compliance with TGO 92 this information should appear under the heading ‘Other information’. Please amend the CHI to include the heading ‘Other Information’.

NB: If the ‘Other information’ heading is included, then the information ‘BioInnova Pty Ltd’ must not appear in a bold font. Alternatively, the sponsor may wish to place a gap between the dosage table and the storage information to indicate the end of the CHI.

8. Deletion of the information ‘protect from light’ from the labelling is not acceptable, since this information is part of the approved shelf life conditions for

the medicine. Please reinstate this information on the carton and bottle labelling.

9. Deletion of the text ‘For professional use only’ is not acceptable, since this medicine should only be used under the direction of a healthcare professional. Please amend the labelling so the text ‘For professional use only’ appears in the CHI under the heading ‘Directions for use’. It is also recommended that this text is duplicated so it also appears under the heading ‘Warnings’ in the CHI.

10. Deletion of the text ‘For topical use only. Not for injection’ is not appropriate, since it describes the proper use of this medicine. Furthermore, for compliance with TGO 92, medicines for topical use should include a warning ‘For external use only’ or words to that effect. As such, please reinstate the previously approved warning ‘For topical use only. Not for injection.’

11. As detailed in the product information document, this medicine ‘should be used once in one patient only and any residue discarded’. As such, deletion of the warning ‘Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner’ is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information ‘They may be repeated as directed only by a physician’ and ‘A new nozzle should be used for each patient. This will remove risks of cross infection between patients’ is not appropriate since it is inconsistent with the proper use of this medicine.

Please amend the labelling to include the warning ‘Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner’ in the CHI under the heading ‘Warnings’.

Please delete the information ‘They may be repeated as directed only by a physician’ and ‘A new nozzle should be used for each patient. This will remove risks of cross infection between patients.’ from the product labelling.

12. Deletion of the text ‘Prime pump 5 times before use’ is not acceptable, since it describes the proper use of this medicine. Please reinstate this information on the carton and bottle labelling. It would be most appropriate under the heading ‘Directions for use’ in the CHI.

13. On the proposed bottle labelling the sentence ‘Not be used in pregnancy’ is not grammatically correct. Please amend the sentence to read ‘Not to be used in pregnancy’.

14. In the CHI under the heading ‘Warnings’, there should be a statement indicating that this medicine is contraindicated in children under 2 years. Please amend the labelling to include the warning ‘Not for use in children under 2 years’ or words to that effect.

Package Insert

15. The sponsor has proposed deletion of the package insert. The information included in the Health Professional – User Guide – Instructions for Assembly of Pump and Actuator to Bottle section of the package insert is considered critical to the correct use of this medicine by healthcare professionals. It is noted that the pump and actuator assembly instructions are not present on the proposed carton/bottle labelling or in product information document (which is commonly used by healthcare professionals for additional information). Deletion of the package insert may make it difficult for healthcare professionals to access this critical information and as such it is not appropriate to delete the package insert for this medicine.

Please retain the currently approved package insert as part of the product labelling for this medicine.

16. Please reinstate the text ‘read enclosed leaflet’ on the carton labelling for this medicine.

Please make only the changes requested above to the product label.

The assessment of the labels, package insert, Product Information and Consumer Medicines Information documents has now been completed and changes other than those shown above will not be accepted prior to approval of the product. Any further label, package insert, Product Information and Consumer Medicines Information document changes may be made by way of a variation application once the product has been approved and registered.

Please forward your response, including amended labels as outlined above within 15 working days **(Due date: 28 November 2019)**.

Please provide your response by email to s22 [redacted] @health.gov.au

Kind regards,

s22

Evaluator – Medicines Evaluation (OTC)

Medicines Regulation Division | Health Products Regulation Group
Complementary & OTC Medicines Branch
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: Therapeutic Goods Administration
PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
To: s22
Subject: FW: OM-2019-01125-1 LIDOPHENYL; RFI for C2 Application [SEC=OFFICIAL]
Date: Thursday, 28 November 2019 2:01:14 PM
Attachments: image001.png
n004445.zip

Hi s22

Here's a response to an RFI for one of s22 applications that you now have.

Thanks
s22

From: s22 @bioinnova.com.au>
Sent: Thursday, 28 November 2019 1:29 PM
To: s22 @health.gov.au>; s22
s22 @health.gov.au>
Subject: Re: OM-2019-01125-1 LIDOPHENYL; RFI for C2 Application [SEC=OFFICIAL]

Dear s22
Please find attached our response for the OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736).

Please let me know if you need any further information.

Kind regards,
s22

On Fri, Nov 22, 2019 at 11:30 AM s22 @bioinnova.com.au> wrote:

> Dear s22
> In addition to below email, we would like to inform that in BP term being use for API is lidocaine. Now since we are using term lignocaine in trade name and carton can we please use Lidocaine instead?
> After your advise we will change the name in trade name and cartons.
>
> Regards
> s22
>
>
>
> On Thu, Nov 21, 2019, 11:37 AM s22 @bioinnova.com.au> wrote:
>
> > Dear s22
> >
> > We are working on the revising labels as per your below email However, we would like to inform on the below queries. Our earlier registered formulation was 2.5ml bottle and hence it was a single dose so it was recommended to discard after use. Now we have 50mL pack the same as an innovator and it is not a single dose. Hence it is recommended to use new nozzle for each patient.
> > We request you to please allow us to keep the below information on the proposed label.

11. As detailed in the product information document, this medicine 'should be used once in one patient only and any residue discarded'. As such, deletion of the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients' is not appropriate since it is inconsistent with the proper use of this medicine.

Please amend the labelling to include the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' in the CHI under the heading 'Warnings'.

Please delete the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients.' from the product labelling.

Kind regards,

s22

BioInnova Pty Ltd

s22

On Thu, Nov 7, 2019 at 2:38 PM s22 <s22 @health.gov.au> wrote:

Dear s22

RE: OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736)

I refer to your application for a grouped change in proprietary name from LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION to LidoPhenyl (Submission ID OM-2019-01125-1, file 2013/014736).

Initial evaluation of this application is now complete and I wish to advise that the following matters need to be addressed before this application is finalised:

Product Name

1. The proposed name ‘LidoPhenyl’ is acceptable. However, for consistency with ARTG naming conventions the product name will be amended to ‘LIDOPHENYL spray bottle’. Please log-in to eBS to verify the product name.

Labelling

2. As per TGO 92, the product name and active ingredient information should appear as a cohesive unit on the main label and must not be interrupted by information. The proposed main label is not acceptable as it includes the text ‘Anaesthetic Vasoconstrictor Nasal Spray’ and a large face graphic between the product name and the active ingredient information. Please amend the main label for the carton and bottle labelling so the product name and active ingredients appear as a cohesive unit.

3. As per TGO 92, the quantity of the active ingredient for a metered dose product is the quantity delivered per actuation. Please amend the unit presentation of the active ingredients strengths from mg/mL to mg/actuation on the carton (including in the CHI) and bottle labelling.

4. As per TGO 92, for a non-pressurised metered dose preparation, the quantity of the medicine is the minimum number of deliverable doses in the container. Please amend the presentation of the medicine quantity from the volume in mL to the minimum number of deliverable doses, e.g. no. of sprays.

5. On the proposed carton label under the heading ‘Directions for use’, the subheading ‘dosage’ has the same formatting as the required CHI headings. The presentation of the subheading ‘dosage’ should be amended so it can be differentiated from the required CHI headings.

6. As per TGO 92, the CHI should be presented in one dark coloured text on a white or light background. Furthermore, as per the TGO 91 and TGO 92 medicine labels guidance document, colours and bold font should not be used to highlight information in the CHI. Under the sub-heading ‘Dosage’ in

the dosing table, the age groups appear in bold green text and the dosing table borders appear in a light orange colour. For compliance with TGO 92, please amend the dosing table so the text appears in black non-bolded font and amend the colour of the dosing table borders to black.

7. The storage information and distributor information in the CHI appear under the heading ‘Directions for use’. For compliance with TGO 92 this information should appear under the heading ‘Other information’. Please amend the CHI to include the heading ‘Other Information’.

NB: If the ‘Other information’ heading is included, then the information ‘BioInnova Pty Ltd’ must not appear in a bold font. Alternatively, the sponsor may wish to place a gap between the dosage table and the storage information to indicate the end of the CHI.

8. Deletion of the information ‘protect from light’ from the labelling is not acceptable, since this information is part of the approved shelf life conditions for the medicine. Please reinstate this information on the carton and bottle labelling.

9. Deletion of the text ‘For professional use only’ is not acceptable, since this medicine should only be used under the direction of a healthcare professional. Please amend the labelling so the text ‘For professional use only’ appears in the CHI under the heading ‘Directions for use’. It is also recommended that this text is duplicated so it also appears under the heading ‘Warnings’ in the CHI.

10. Deletion of the text ‘For topical use only. Not for injection’ is not appropriate, since it describes the proper use of this medicine. Furthermore, for compliance with TGO 92, medicines for topical use should include a warning ‘For external use only’ or words to that effect. As such, please reinstate the previously approved warning ‘For topical use only. Not for injection.’

11. As detailed in the product information document, this medicine ‘should be used once in one patient only and any residue discarded’. As such, deletion of the warning ‘Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner’ is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information ‘They may be repeated as directed only by a physician’ and ‘A new nozzle should be used for each patient. This will remove risks of cross infection between patients’ is not appropriate since it is inconsistent with the proper use of this medicine.

Please amend the labelling to include the warning ‘Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner’ in the CHI under the heading ‘Warnings’.

Please delete the information ‘They may be repeated as directed only by a physician’ and ‘A new nozzle should be used for each patient. This will remove risks of cross infection between patients.’ from the product labelling.

12. Deletion of the text ‘Prime pump 5 times before use’ is not acceptable, since it describes the proper use of this medicine. Please reinstate this information on the carton and bottle labelling. It would be most appropriate under the heading ‘Directions for use’ in the CHI.

13. On the proposed bottle labelling the sentence ‘Not be used in pregnancy’ is not grammatically correct. Please amend the sentence to read ‘Not to be used in pregnancy’.

14. In the CHI under the heading ‘Warnings’, there should be a statement indicating that this medicine is contraindicated in children under 2 years. Please amend the labelling to include the warning ‘Not for use in children under 2 years’ or words to that effect.

Package Insert

15. The sponsor has proposed deletion of the package insert. The information included in the Health Professional – User Guide – Instructions for Assembly of Pump and Actuator to Bottle section of the package insert is considered critical to the correct use of this medicine by healthcare professionals. It is noted that the pump and actuator assembly instructions are not present on the proposed carton/bottle labelling or in product information document (which is commonly used by healthcare professionals for additional information). Deletion of the package insert may make it difficult for healthcare professionals to access this critical information and as such it is not appropriate to delete the package insert for this medicine.

Please retain the currently approved package insert as part of the product labelling for this medicine.

16. Please reinstate the text ‘read enclosed leaflet’ on the carton labelling for this medicine.

Please make only the changes requested above to the product label.

The assessment of the labels, package insert, Product Information and Consumer Medicines Information documents has now been completed and changes other than those shown above will not be accepted prior to approval of the product. Any further label, package insert, Product Information and Consumer Medicines Information document changes may be made by way of a variation application once the product has been approved and registered.

Please forward your response, including amended labels as outlined above within 15 working days **(Due date: 28 November 2019)**.

Please provide your response by email to s22 [redacted] @health.gov.au

Kind regards,

s22 [redacted]

Evaluator – Medicines Evaluation (OTC)

Medicines Regulation Division | Health Products Regulation Group
Complementary & OTC Medicines Branch
Australian Government Department of Health
T: s22 [redacted] | E: s22 [redacted] @health.gov.au
Location: Therapeutic Goods Administration
PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

28 November 2019

Re: Application No: OM-2019-01125-1
Response to request for additional information.

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Supplementary Infomation
Sequence number	0003
Related sequence	0002
Date	2019.11.28
Electronic media	Electronic via eBS portal
Submission size	~ 2 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Please find herewith our response to the query received for OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736).

Supporting documentation:

Module 1 Response and Proposed labels

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019
0003	0002	Supplementary information	Response to request for information	November 2019

OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736)

Product Name

1. The proposed name ‘LidoPhenyl’ is acceptable. However, for consistency with ARTG naming conventions the product name will be amended to ‘LIDOPHENYL spray bottle’. Please log-in to eBS to verify the product name.

Response: We acknowledge the comment and we will verify the name.

Labelling

2. As per TGO 92, the product name and active ingredient information should appear as a cohesive unit on the main label and must not be interrupted by information. The proposed main label is not acceptable as it includes the text ‘Anaesthetic Vasoconstrictor Nasal Spray’ and a large face graphic between the product name and the active ingredient information. Please amend the main label for the carton and bottle labelling so the product name and active ingredients appear as a cohesive unit.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

3. As per TGO 92, the quantity of the active ingredient for a metered dose product is the quantity delivered per actuation. Please amend the unit presentation of the active ingredients strengths from mg/mL to mg/actuation on the carton (including in the CHI) and bottle labelling.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

4. As per TGO 92, for a non-pressurised metered dose preparation, the quantity of the medicine is the minimum number of deliverable doses in the container. Please amend the presentation of the medicine quantity from the volume in mL to the minimum number of deliverable doses, e.g. no. of sprays.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

5. On the proposed carton label under the heading ‘Directions for use’, the subheading ‘dosage’ has the same formatting as the required CHI headings. The presentation of the subheading ‘dosage’ should be amended so it can be differentiated from the required CHI headings.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

6. As per TGO 92, the CHI should be presented in one dark coloured text on a white or light background. Furthermore, as per the TGO 91 and TGO 92 medicine labels guidance document, colours and bold font should not be used to highlight information in the CHI. Under the sub-heading ‘Dosage’ in the dosing table, the age groups appear in bold green text and the dosing table borders appear in a light orange colour. For compliance with TGO 92, please amend the dosing table so the text appears in black non-bolded font and amend the colour of the dosing table borders to black.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

7. The storage information and distributor information in the CHI appear under the heading ‘Directions for use’. For compliance with TGO 92 this information should appear under the heading ‘Other information’. Please amend the CHI to include the heading ‘Other Information’. NB: If the ‘Other information’ heading is included, then the information ‘BioInnova Pty Ltd’ must not appear in a bold font. Alternatively, the sponsor may wish to place a gap between the dosage table and the storage information to indicate the end of the CHI.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

8. Deletion of the information ‘protect from light’ from the labelling is not acceptable, since this information is part of the approved shelf life conditions for the medicine. Please reinstate this information on the carton and bottle labelling.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

9. Deletion of the text ‘For professional use only’ is not acceptable, since this medicine should only be used under the direction of a healthcare professional. Please amend the labelling so the text ‘For professional use only’ appears in the CHI under the heading ‘Directions for use’. It is also recommended that this text is duplicated so it also appears under the heading ‘Warnings’ in the CHI.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

10. Deletion of the text ‘For topical use only. Not for injection’ is not appropriate, since it describes the proper use of this medicine. Furthermore, for compliance with TGO 92, medicines for topical use should include a warning ‘For external use only’ or words to that effect. As such, please reinstate the previously approved warning ‘For topical use only. Not for injection.’

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

11. As detailed in the product information document, this medicine ‘should be used once in one patient only and any residue discarded’. As such, deletion of the warning

'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients' is not appropriate since it is inconsistent with the proper use of this medicine.

Please amend the labelling to include the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' in the CHI under the heading 'Warnings'.

Please delete the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients.' from the product labelling.

Response: Our earlier registered formulation was 2.5ml bottle and hence it was a single dose so it was recommended to discard after use. Now we have 50mL pack the same as an innovator and it is not a single dose. Hence it is recommended to use new nozzle for each patient.
We request you to please allow us to keep the below information on the proposed label. If needed, we can revise the Product Information accordingly.
Further, we also want to change the term from Lignocaine to Lidocaine as per Ph.eur monograph and TGA's recommendation https://www.tga.gov.au/updating-medicine-ingredient-names-list-affected-ingredients.
We kindly request to change the name. after your confirmation, we will revise the PI/CMI and send to you.

12. Deletion of the text 'Prime pump 5 times before use' is not acceptable, since it describes the proper use of this medicine. Please reinstate this information on the carton and bottle labelling. It would be most appropriate under the heading 'Directions for use' in the CHI.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

13. On the proposed bottle labelling the sentence 'Not be used in pregnancy' is not grammatically correct. Please amend the sentence to read 'Not to be used in pregnancy'.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

14. In the CHI under the heading 'Warnings', there should be a statement indicating that this medicine is contraindicated in children under 2 years. Please amend the labelling to include the warning 'Not for use in children under 2 years' or words to that effect.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

Package Insert

15. The sponsor has proposed deletion of the package insert. The information included in the Health Professional – User Guide – Instructions for Assembly of Pump and Actuator to Bottle section of the package insert is considered critical to the correct use of this medicine by healthcare professionals. It is noted that the pump and actuator assembly instructions are not present on the proposed carton/bottle labelling or in product information document (which is commonly used by healthcare professionals for additional information). Deletion of the package insert may make it difficult for healthcare professionals to access this critical information and as such it is not appropriate to delete the package insert for this medicine.

Please retain the currently approved package insert as part of the product labelling for this medicine.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

16. Please reinstate the text ‘read enclosed leaflet’ on the carton labelling for this medicine.

Response: We acknowledge the comment. Please refer updated labels in module 1.3.3.

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl
Spray

Lidocaine hydrochloride
2500mcg/actuation
Phenylephrine hydrochloride
250mcg/actuation

Anaesthetic Vasoconstrictor
Nasal Spray
800 Metered Doses

Peppermint Flavour

50 mL

AUST R 225750

USES:
- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper airways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS: These doses are to be administered once only. Repeated as directed only by a physician. Not for use in children under age of 2 years. Must be used with caution in patients who have cardiovascular disease. Not to be used in pregnancy.

DIRECTIONS FOR USE:
Prime pump 5 times before use.
Each squirt contains 100 microlitres.

Recommended Dosages:
Dosage for nasal and pharyngeal administration:
Adults and children over 12 years:
Up to 5 squirts per nostril
8 to 12 years: 3 squirts per nostril
4-8 years: 2 squirts per nostril
2-4 years: 1 squirt pernostril

LP Nozzles™ are available in two length and can be purchased separately from local distributor.
- S-100 mm long
- L-200 mm long

OTHER INFORMATION
Store below 25°C. Protect from light.
Mfg Lic No.:
Distributor:
BioInnova Pty. Ltd.
U-37, 14 Loyalty Road,North Rocks,
NSW 2151 Australia
Email: info@bioinnova.com.au

B. No. :
MFD :
EXP :

Unvarnished Area (OPZ)

100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

NOZZLE SUPPLY

One LP Nozzle™ is available inside. LP Nozzle™ available separately. A new nozzle should be used for each patient to avoid risks of cross infection between Patients.

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:
ACTIVE INGREDIENT:
Lidocaine hydrochloride 50mg/mL (5%) and Phenylephrine hydrochloride 5mg/mL (0.5%)

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:
These doses are to be administered once only. Repeated as directed only by a physician. Not for use in children under age of 2 years. Must be used with caution in patients who have cardiovascular disease. Not to be used in pregnancy.

For professional use only.
For external use only.
For topical use only.

9 349777 008637

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl Spray

Lidocaine hydrochloride 2500 mcg / actuation and Phenylephrine hydrochloride 250 mcg /actuation.

Anaesthetic Vasoconstrictor
Nasal Spray

800 Metered Doses

Peppermint Flavour

50 mL

AUST R 225750

DIRECTIONS FOR USE:
Prime pump 5 times before use.
Each squirt contains 100 microlitres.
For professional use only.
For topical use only.
Not for injection.
Read enclosed leaflet.

Recommended Dosages:
Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

OTHER INFORMATION
Store below 25°C. Protect from light.

Mfg Lic No.:

Distributor:
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks, NSW 2151
Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT

From: s22
To: s22
Cc: s22
Subject: Re: OM-2019-01125-1 LIDOPHENYL; RFI (supplementary) [SEC=OFFICIAL]
Date: Monday, 20 January 2020 10:13:34 PM
Attachments: image002.png
n004445.zip

Dear s22
Thank you for evaluating our response.
Please find attached our response to your further request.
Please let us know if there are any further questions.
Thank you.

Sincerely,
s22
M: s22
Phone: s22 Fax: s22
E: s22 @seedpharma.com
www.seedpharma.com

On Fri, Jan 10, 2020 at 5:28 AM s22 @health.gov.au> wrote:

> Good morning s22
>
> Your RFI response for this application has been received with thanks.
>
> To answer your questions, the transition period for the use of International Non-proprietary Names (INN) ends in April 2020. However, products containing lignocaine requiring the dual labelling of "lidocaine (lignocaine)" until 2023.
>
> To this end, the labelling (carton and bottle), PI and CMI will need to be updated to display the dual name for lidocaine.
>
> The current presentation of the information on the side carton label panel regarding the replaceable nozzle is acceptable and the request made in the initial RFI to display "discard after use" information will not be pursued.
>
> Additional changes required for the labelling are outlined below:
>
> - The CHI section under the heading "ACTIVE INGREDIENTS" requires amendment so that the strengths of the active ingredients match the presentation of the main label (2500mcg/ actuation and 250mcg/ actuation, respectively).
> -

The graphic element on the main label panel between the medicine name and active ingredients creates a gap which is considered to be in contravention of section 9(3)b of the labelling order TGO92. The sponsor is asked to remove the gold line and move the active ingredient information into left alignment on the label. For consistency, a design identical to that of the bottle label will be acceptable.

- As per section 8(1)k of the labelling order TGO92 the bottle label requires the addition of the warning statements "For external use only" and "For professional use only".

Kindest regards,

s22 [redacted]
Evaluator/ Pharmacist
Medicines Evaluation (OTC)
Complementary and OTC Medicines Branch

Phone: s22 [redacted]
Email: s22 [redacted] @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22 [redacted] @bioinnova.com.au>
Sent: Friday, 22 November 2019 11:30 AM
To: s22 [redacted] @health.gov.au>
Subject: Re: OM-2019-01125-1 LIDOPHENYL; RFI for C2 Application [SEC=OFFICIAL]

Dear s22 [redacted]

In addition to below email, we would like to inform that in BP term being use for API is lidocaine. Now since we are using term lignocaine in trade name and carton can we please use Lidocaine instead?

After your advise we will change the name in trade name and cartons.

Regards

s22

On Thu, Nov 21, 2019, 11:37 AM s22 @bioinnova.com.au> wrote:

Dear s22

We are working on the revising labels as per your below email However, we would like to inform on the below queries. Our earlier registered formulation was 2.5ml bottle and hence it was a single dose so it was recommended to discard after use. Now we have 50mL pack the same as an innovator and it is not a single dose. Hence it is recommended to use new nozzle for each patient.

We request you to please allow us to keep the below information on the proposed label.

> 11. As detailed in the product information document, this medicine 'should be used once in one patient only and any residue discarded'. As such, deletion of the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients' is not appropriate since it is inconsistent with the proper use of this medicine.
>
> Please amend the labelling to include the warning 'Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner' in the CHI under the heading 'Warnings'.
>
> Please delete the information 'They may be repeated as directed only by a physician' and 'A new nozzle should be used for each patient. This will remove risks of cross infection between patients.' from the product labelling.

Kind regards,

s22

BioInnova Pty Ltd

s22

On Thu, Nov 7, 2019 at 2:38 PM s22 s22 @health.gov.au> wrote:

Dear s22

RE: OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736)

I refer to your application for a grouped change in proprietary name from LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION to LidoPhenyl (Submission ID OM-2019-01125-1, file 2013/014736).

Initial evaluation of this application is now complete and I wish to advise that the following matters need to be addressed before this application is finalised:

Product Name

1. The proposed name 'LidoPhenyl' is acceptable. However, for consistency with ARTG naming conventions the product name will be amended to 'LIDOPHENYL spray bottle'. Please log-in to eBS to verify the product name.

Labelling

2. As per TGO 92, the product name and active ingredient information should appear as a cohesive unit on the main label and must not be interrupted by information. The proposed main label is not acceptable as it includes the text 'Anaesthetic Vasoconstrictor Nasal Spray' and a large face graphic between the product name and the active ingredient information. Please amend the main label for the carton and bottle labelling so the

product name and active ingredients appear as a cohesive unit.

3. As per TGO 92, the quantity of the active ingredient for a metered dose product is the quantity delivered per actuation. Please amend the unit presentation of the active ingredients strengths from mg/mL to mg/actuation on the carton (including in the CHI) and bottle labelling.

4. As per TGO 92, for a non-pressurised metered dose preparation, the quantity of the medicine is the minimum number of deliverable doses in the container. Please amend the presentation of the medicine quantity from the volume in mL to the minimum number of deliverable doses, e.g. no. of sprays.

5. On the proposed carton label under the heading ‘Directions for use’, the subheading ‘dosage’ has the same formatting as the required CHI headings. The presentation of the subheading ‘dosage’ should be amended so it can be differentiated from the required CHI headings.

6. As per TGO 92, the CHI should be presented in one dark coloured text on a white or light background. Furthermore, as per the TGO 91 and TGO 92 medicine labels guidance document, colours and bold font should not be used to highlight information in the CHI. Under the sub-heading ‘Dosage’ in the dosing table, the age groups appear in bold green text and the dosing table borders appear in a light orange colour. For compliance with TGO 92, please amend the dosing table so the text appears in black non-bolded font and amend the colour of the dosing table borders to black.

7. The storage information and distributor information in the CHI appear under the heading ‘Directions for use’. For compliance with TGO 92 this information should appear under the heading ‘Other information’. Please amend the CHI to include the heading ‘Other Information’.

NB: If the ‘Other information’ heading is included, then the information ‘BioInnova Pty Ltd’ must not appear in a bold font. Alternatively, the sponsor may wish to place a gap between the dosage table and the storage information to indicate the end of the CHI.

8. Deletion of the information ‘protect from light’ from the labelling is not acceptable, since this information is part of the approved shelf life conditions for the medicine. Please reinstate this information on the carton and bottle labelling.

9. Deletion of the text ‘For professional use only’ is not acceptable, since this medicine should only be used under the direction of a healthcare professional. Please amend the labelling so the text ‘For professional use only’ appears in the CHI under the heading ‘Directions for use’. It is also recommended that this text is duplicated so it also appears under the heading ‘Warnings’ in the CHI.

10. Deletion of the text ‘For topical use only. Not for injection’ is not appropriate, since it describes the proper use of this medicine. Furthermore, for compliance with TGO 92, medicines for topical use should include a warning ‘For external use only’ or words to that effect. As such, please reinstate the previously approved warning ‘For topical use only. Not for injection.’

11. As detailed in the product information document, this medicine ‘should be used once in one patient only and any residue discarded’. As such, deletion of the warning ‘Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner’ is not acceptable, since it describes the proper use of this medicine. Similarly, the addition of the information ‘They may be repeated as directed only by a physician’ and ‘A new nozzle should be used for each patient. This will remove risks of cross infection between patients’ is not appropriate since it is inconsistent with the proper use of this medicine.

Please amend the labelling to include the warning ‘Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner’ in the CHI under the heading ‘Warnings’.

Please delete the information ‘They may be repeated as directed only by a physician’ and ‘A new nozzle should be used for each patient. This will remove risks of cross infection between patients.’ from the product labelling.

12. Deletion of the text ‘Prime pump 5 times before use’ is not acceptable, since it describes the proper use of this medicine. Please reinstate this information on the carton and bottle labelling. It would be most appropriate under the heading ‘Directions for use’ in the CHI.

13. On the proposed bottle labelling the sentence ‘Not be used in pregnancy’ is not grammatically correct. Please amend the sentence to read ‘Not to be used in pregnancy’.

14. In the CHI under the heading ‘Warnings’, there should be a statement indicating that this medicine is contraindicated in children under 2 years. Please amend the labelling to include the warning ‘Not for use in children under 2 years’ or words to that effect.

Package Insert

15. The sponsor has proposed deletion of the package insert. The information included in the Health Professional – User Guide – Instructions for Assembly of Pump and Actuator to Bottle section of the package insert is considered critical to the correct use of this medicine by healthcare professionals. It is noted that the pump and actuator assembly instructions are not present on the proposed carton/bottle labelling or in product information document (which is commonly used by healthcare professionals for additional information). Deletion of the package insert may make it difficult for healthcare professionals to access this critical information and as such it is not appropriate to delete the package insert for this medicine.

Please retain the currently approved package insert as part of the product labelling for this medicine.

16. Please reinstate the text ‘read enclosed leaflet’ on the carton labelling for this medicine.

Please make only the changes requested above to the product label.

The assessment of the labels, package insert, Product Information and Consumer Medicines Information documents has now been completed and changes other than those shown above will not be accepted prior to approval of the product. Any further label, package insert, Product Information and Consumer Medicines Information document changes may be made by way of a variation application once the product has been approved and registered.

Please forward your response, including amended labels as outlined above within 15 working days **(Due date: 28 November 2019)**.

Please provide your response by email to s22 @health.gov.au

Kind regards,

s22

Evaluator – Medicines Evaluation (OTC)

Medicines Regulation Division | Health Products Regulation Group

Complementary & OTC Medicines Branch

Australian Government Department of Health

T: s22 | E: s22 @health.gov.au

Location: Therapeutic Goods Administration

PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

20 January 2020

Re: Application No: OM-2019-01125-1
Response to request for additional information.

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Supplementary Infomation
Sequence number	0004
Related sequence	0003
Date	2020.1.20
Electronic media	Electronic via eBS portal
Submission size	~ 2 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Please find herewith our response to the query received for OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736).

Supporting documentation:

Module 1 Response and Proposed labels and PI/CMI.

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019
0003	0002	Supplementary information	Response to request for information	November 2019
0004	0003	Supplementary information	Response to request for information	January 2020

OM-2019-01125-1 LidoPhenyl Spray (File 2013/014736)

Question 1:

The labelling (carton and bottle), PI and CMI will need to be updated to display the dual name for lidocaine.

Response:

We acknowledge the comment. Please refer updated PI/CMI in module 1.3.1 and labels in module 1.3.3.

Question 2:

The current presentation of the information on the side carton label panel regarding the replaceable nozzle is acceptable and the request made in the initial RFI to display “discard after use” information will not be pursued.

Additional changes required for the labelling are outlined below:

- The CHI section under the heading “ACTIVE INGREDIENTS” requires amendment so that the strengths of the active ingredients match the presentation of the main label (2500mcg/ actuation and 250mcg/ actuation, respectively).
- The graphic element on the main label panel between the medicine name and active ingredients creates a gap which is considered to be in contravention of section 9(3)b of the labelling order TGO92. The sponsor is asked to remove the gold line and move the active ingredient information into left alignment on the label. For consistency, a design identical to that of the bottle label will be acceptable.
- As per section 8(1)k of the labelling order TGO92 the bottle label requires the addition of the warning statements “For external use only” and “For professional use only”.

Response:

We acknowledge the comment. Please refer updated labels in module 1.3.3.

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
A new nozzle should be used for each patient to avoid risks of cross infection between patients.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lidocaine **(**lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents.
2.5mL Pack: For single use in one patient only. Any unused product should be discarded.
50mL Pack: A New nozzle should be used for each patient to avoid risks of cross infection between patients.

6.5 NATURE AND CONTENTS OF CONTAINER

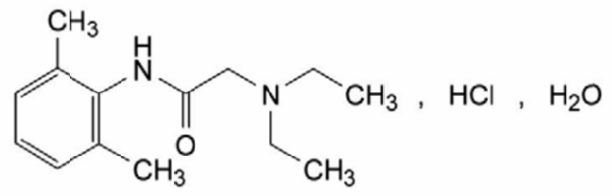
Pump actuated topical solution:
Lidocaine (lignocaine) 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

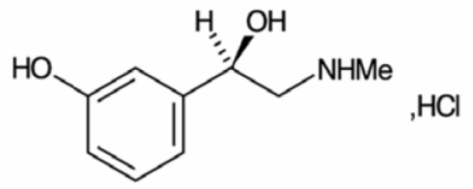
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lidocaine (l~~l~~ignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lidocaine (l~~l~~ignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
~~For single use in one patient only.~~
A new nozzle should be used for each patient to avoid risks of cross infection between patients.

Formatted: Indent: Left: 0.25 cm

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (~~L~~lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lidocaine (~~L~~lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Formatted: Font: (Default) Times New Roman, 12 pt

Use in renal impairment

Metabolites of Lidocaine (lignocaine-) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (~~L~~lignocaine) can have additive effects or antagonistic effects. **Suxamethonium**- Lidocaine (~~L~~lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (~~L~~lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2**- Lidocaine (~~L~~lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (~~L~~lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) ~~Lignocaine~~ hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine)~~lignocaine~~. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) ~~Lignocaine~~ **hydrochloride**. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) ~~lignocaine~~ and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) ~~Lignocaine~~ hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) ~~lignocaine~~ and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine)~~lignocaine~~. Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

Formatted: Font: Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold

5.2 PHARMACOKINETIC PROPERTIES

Formatted: Normal, Space After: 8 pt, Line spacing: Multiple 1.08 li

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents.
2.5mL Pack: For single use in one patient only. Any unused product should be discarded.
50mL Pack: A New nozzle should be used for each patient to avoid risks of cross infection between patients.

6.5 NATURE AND CONTENTS OF CONTAINER

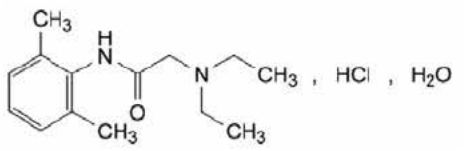
Pump actuated topical solution:
Lidocaine (lignocaine) ~~Lignocaine~~ 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

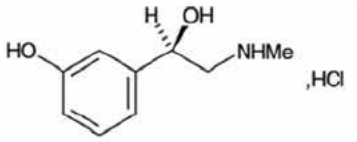
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



Formatted: Font: Not Bold

Formatted: Font: (Default) Times New Roman, 12 pt, Not Bold, English (United States)

Formatted: Font: (Default) Times New Roman, 12 pt, English (United States)

Formatted: Font: (Default) Times New Roman, 12 pt, Not Bold, English (United States)

Formatted: Font: (Default) Times New Roman, 12 pt, English (United States)

CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

Formatted: Indent: Left: 0 cm

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size

LidoPhenyl spray aerosol (Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v)

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients Lidocaine (lignocaine) hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lidocaine (lignocaine)hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lidocaine (lignocaine)Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lidocaine (lignocaine) the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of Lidocaine (lignocaine) on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of Lidocaine (lignocaine) (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of Lidocaine (lignocaine) in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

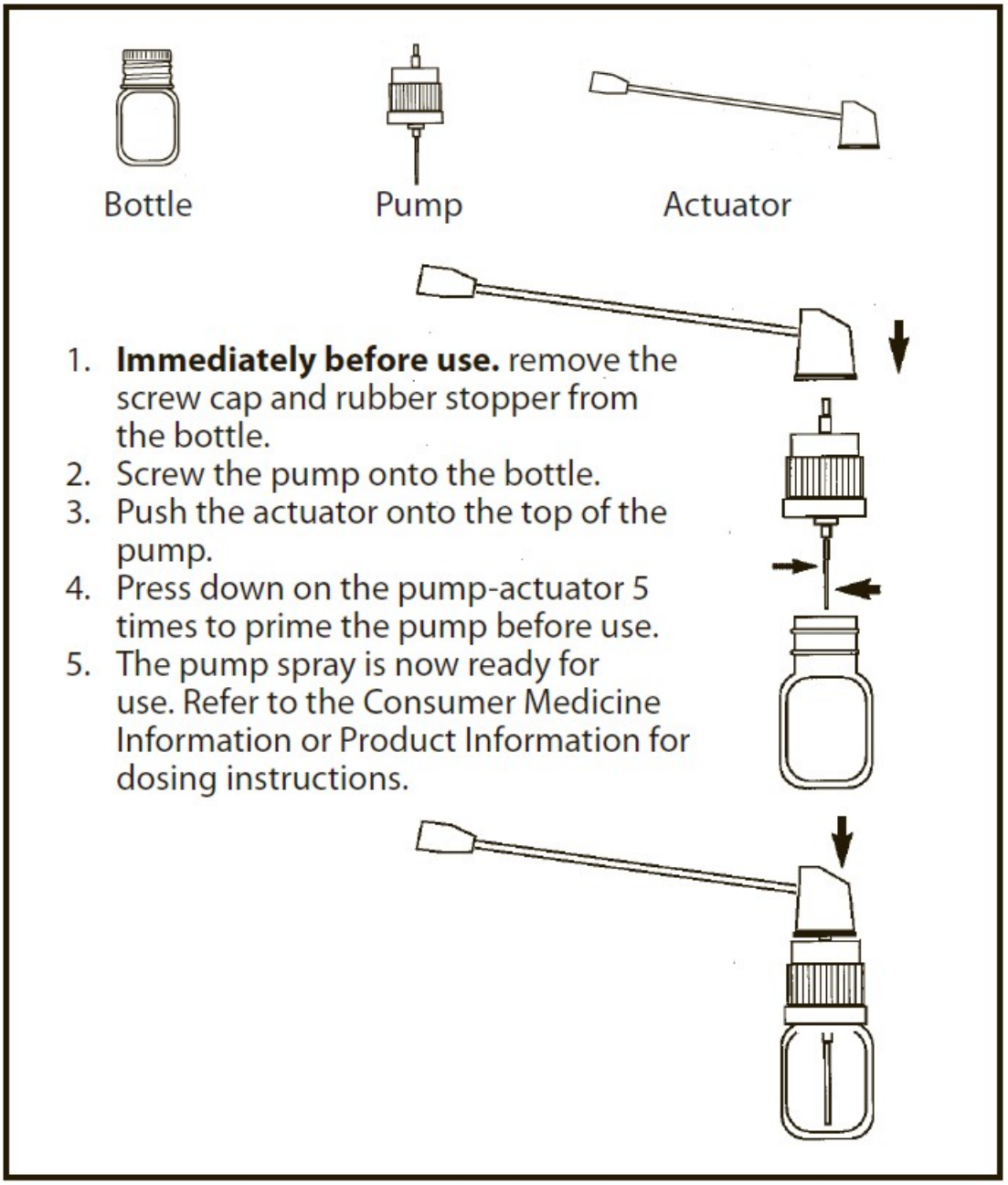
Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

This leaflet was prepared September 2019.

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip

A New nozzle should be used for each patient to avoid risks of cross infection between patients.

LidoPhenyl spray aerosol (Lidocaine (~~L~~lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v) ~~Topical Solution~~

Formatted: Font: (Default) Arial Black, (Intl) Arial, English (United States), Check spelling and grammar

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients Lidocaine (lignocaine) hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lidocaine (lignocaine)~~Lignocaine~~ hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lidocaine (lignocaine) ~~Lignocaine~~ hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lidocaine (lignocaine)~~Lignocaine~~ Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may becomepregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lidocaine (lignocaine)~~Lignocaine~~ the anaesthetic agent may make the effect of any

heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of Lidocaine (lignocaine)~~lignocaine~~ on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of Lidocaine (lignocaine)~~lignocaine~~ (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lidocaine (lignocaine)~~Lignocaine~~ Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of Lidocaine (lignocaine)~~lignocaine~~ in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lidocaine (lignocaine)~~Lignocaine~~ Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

Lidocaine (lignocaine)~~Lignocaine~~ Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

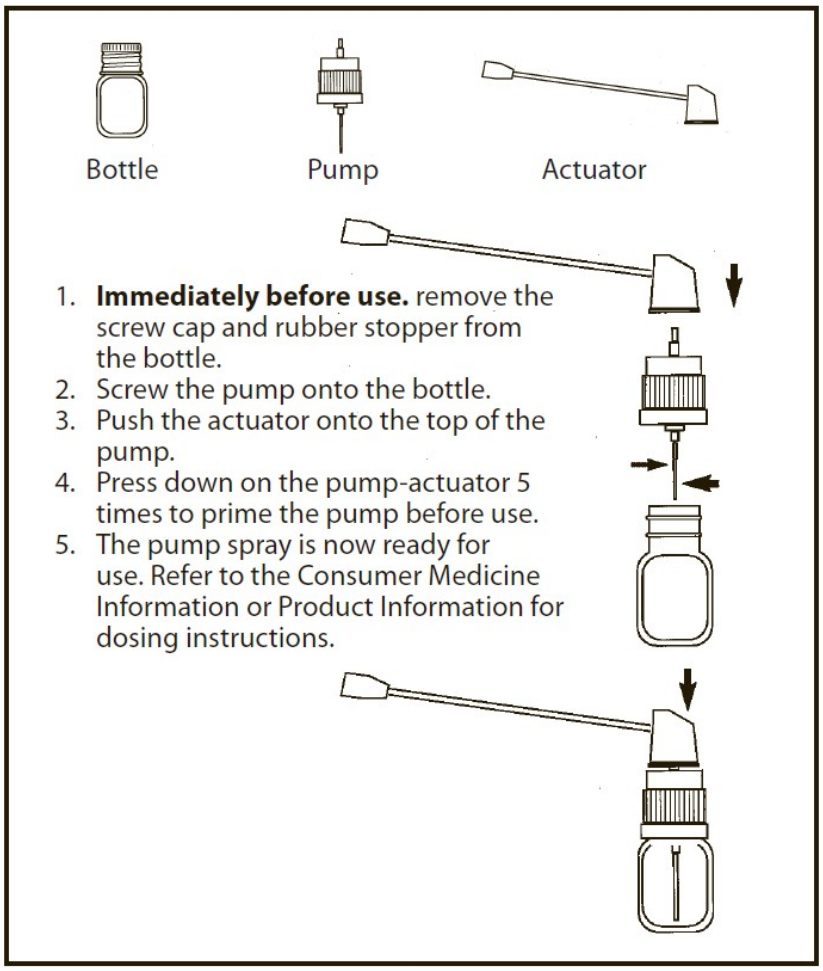
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au
~~Luminarie Pty Ltd~~
~~Baulkham Hills~~
~~NSW 2153~~
~~Australia~~
~~http://www.luminarie.com.au~~

This leaflet was prepared ~~June~~ September 2019.

Formatted: Indent: Left: 0.25 cm

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

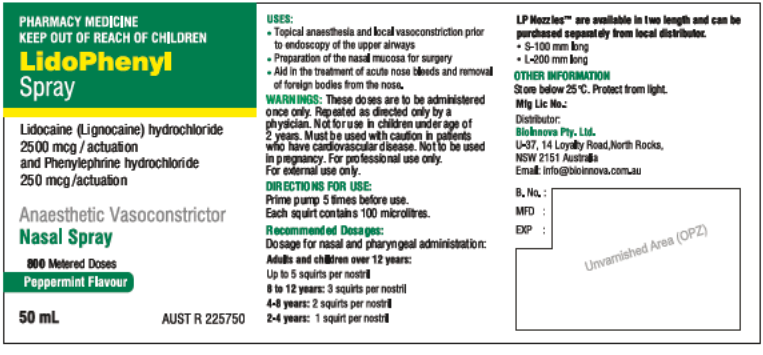
Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip
~~The product is sterile until opened, and contains no preservative.~~
~~Use once in one patient only and discard the bottle and any remaining solution in an~~

~~appropriate manner.~~

A New nozzle should be used for each patient to avoid risks of cross infection between patients.

Formatted: Indent: Left: 0.5 cm



100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

NOZZLE SUPPLY

One LP Nozzle™ is available inside. LP Nozzle™ available separately. A new nozzle should be used for each patient to avoid risks of cross infection between Patients.

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:

ACTIVE INGREDIENT:

Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation
and Phenylephrine hydrochloride 250 mcg /actuation

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:

These doses are to be administered once only. Repeated as directed only by a physician. Not for use in children under age of 2 years. Must be used with caution in patients who have cardiovascular disease. Not to be used in pregnancy.

For professional use only.
For external use only.
For topical use only.

9 349777 008637

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl Spray

Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation
and Phenylephrine hydrochloride 250 mcg /actuation

Anaesthetic Vasoconstrictor
Nasal Spray

800
Metered Doses

Peppermint Flavour

50 mL

AUST R 225750

DIRECTIONS FOR USE:

Prime pump 5 times before use.
Each squirt contains 100 microlitres.
For professional use only.
For topical use only.
Not for injection.
Read enclosed leaflet.

Recommended Dosages:
Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

OTHER INFORMATION

Store below 25°C. Protect from light.

Mfg Lic No.:

Distributor:
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks, NSW 2151
Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT

From: s22
To: s22
Cc: COMB Systems
Subject: OM-2019-01125-1 LIDOPHENYL SPRAY bottle; C2 (grouping) Approval letter [SEC=OFFICIAL]
Date: Tuesday, 28 January 2020 4:15:56 PM
Attachments: OM-2019-01125-1 LIDOPHENYL SPRAY bottle; C2 Approval letter.PDF

Dear s22

Re: OM-2019-01125-1 LIDOPHENYL SPRAY bottle

Please find attached an electronic copy of the **approval letter** for this application. This will be the only copy provided unless otherwise requested.

Before the goods can be included in the Register, you are required to either:

- Notify the Secretary using the approved form that the patent certification under subsection 26B(1) is not required in relation to the application; OR
- Provide a certification required under subsection 26B(1) of the Act.

The requirements for the patent certificates does not apply to applicants for registration of medicines who are not required to submit evidence or information to establish the safety or efficacy of the goods as part of the registration process. In these circumstances, the applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the application

The notification form and patent certificate can be downloaded via the TGA website. Please email a copy to otc.medicines@health.gov.au

As noted above, a Certificate of Registration can only be issued after receipt of the completed and signed form or certificate.

Kindest regards,

s22
Evaluator/ Pharmacist
Medicines Evaluation (OTC)
Complementary and OTC Medicines Branch

Phone: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

Submission ID: OM-2019-01125-1
Reference: D20-89957

The Managing Director
Bioinnova Pty Ltd
s22 [redacted]

Attention: s22 [redacted]

Dear Sir/Madam

APPLICATION UNDER s. 23 TO REGISTER A NEW MEDICINE UNDER s. 25 IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

I refer to your application under section 23 of the *Therapeutic Goods Act 1989* (the Act) dated 8 September 2019 to register LIDOPHENYL SPRAY bottle (the medicine) in the Australian Register of Therapeutic Goods (the ARTG) which, while a separate and distinct good under subsection 16(1) of the Act, is the same as registered medicine LIGNOCAINE HYDROCHLORIDE 5% w/v & PHENYLEPHRINE HYDROCHLORDE 0.5% w/v TOPICAL SOLUTION (AUST R 225750) (the "currently registered medicine") except for the change in medicine name and the subsequent changes to the medicine labelling (in compliance with TGO92), package leaflet and product information.

Decision

As delegate of the Secretary of the Department of Health, I am:

- under subsection 25(3) of the Act, approving the registration of the medicine in the ARTG on the basis that the only difference between the proposed medicine and the currently registered medicine is the change in medicine name and the subsequent changes to the medicine labelling, package leaflet and product information, and
- under subsection 25AB(2) of the Act, notifying you of the decision to register the medicine, and
- under subsection 28(2B) of the Act, applying conditions of registration of the medicine, as outlined under 'Conditions of Registration' below.

The Act can be found online.

Date of effect and supply

Under subsection 16(1) of the Act, the new medicine is a separate and distinct good. However, because you have indicated that the new medicine will replace the existing medicine, the same AUST R number may be used by reason of the Therapeutic Goods (Groups) Order No. 1 of 2001.

The date of effect of the new registration is the date specified in the Certificate of Registration, a copy of which may be obtained via the eBusiness Services (eBS) facilities shortly after receipt of the patent certification requested below. This should be the date included under the heading "date of the most recent amendment" at the end of the approved PI as set out at Attachment 2.

Conditions of registration

The conditions applying to the new registration of the medicine are:

1. Conditions applicable to all therapeutic goods as specified in the current edition of the document "Conditions- standard and specific: Applying to registered or listed therapeutic goods under section 28 of the *Therapeutic Goods Act 1989*", and
2. Conditions applicable to the relevant category and class of therapeutic goods as specified in the current edition of the document " Conditions- standard and specific: Applying to registered or listed therapeutic goods under section 28 of the *Therapeutic Goods Act 1989*"

Action required of you

Before the medicine can be included in the ARTG, you are required to either:

- notify the Secretary using the approved form that the patent certification under subsection 26B(1) of the Act is not required in relation to the application; or
- provide a certificate required under subsection 26B(1) of the Act.

Note:

The requirement for patent certificates does not apply to applicants for registration of medicines who are not required to submit evidence or information to establish the safety or efficacy of the goods as part of the registration process. In these circumstances, the applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the application.

The notification form and patent certificate can be downloaded via the TGA website. You should forward the completed and signed certificate or notification to otc.medicines@health.gov.au. A certificate of registration can only be issued after receipt of the completed and signed certificate or notification.

Review rights

Details of your review rights are at Attachment 1.

Other matters

Copies of the final medicine labels are provided at Attachment 2. Please note that your product labels have not been evaluated for compliance with State and Territory labelling requirements.

The Product Information document* is provided at Attachment 3.

* Note that this Product Information is not of a kind required under the Act to be approved by the Secretary.

The final consumer medicine information is provided at Attachment 4.

You are reminded of the pharmacovigilance reporting requirements as set out in the document "*Pharmacovigilance responsibilities of medicine sponsors – Australian recommendations and requirements*", including the requirement to keep the Australian

pharmacovigilance contact person details up to date through the TGA Business Services electronic portal.

Please note that it is your responsibility to ensure that current Good Manufacturing Practice clearance letters are maintained for all overseas sites of manufacture registered for the products.

Please do not hesitate to contact me if you have any further queries regarding this matter.

Yours faithfully

Signed and authorised by
s22
Delegate of the Secretary
Complementary & OTC Medicines Branch
Email: s22 @health.gov.au

30 January 2020

Attachments:

1. Review rights
2. Labels
3. Product information
4. Consumer medicine information

Attachment 1

Request for reconsideration of an initial decision

The decisions under sections 25 and 28 of the Act are 'initial decisions' within the meaning of section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted. The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and '**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

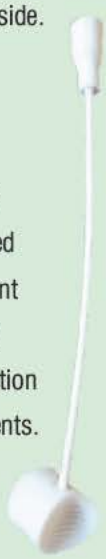
Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

NOZZLE SUPPLY

One LP Nozzle™ is available inside. LP Nozzle™ available separately. A new nozzle should be used for each patient to avoid risks of cross infection between Patients.



LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:

ACTIVE INGREDIENT:

Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation
and Phenylephrine hydrochloride 250 mcg /actuation

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:

These doses are to be administered once only. Repeated as directed only by a physician. Not for use in children under age of 2 years. Must be used with caution in patients who have cardiovascular disease. Not to be used in pregnancy.

For professional use only.
For external use only.
For topical use only.

9 349777 008637

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl Spray

Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation
and Phenylephrine hydrochloride 250 mcg /actuation

Anaesthetic Vasoconstrictor
Nasal Spray

800
Metered Doses

Peppermint Flavour

50 mL

AUST R 225750

DIRECTIONS FOR USE:

Prime pump 5 times before use.
Each squirt contains 100 microlitres.
For professional use only.
For topical use only.
Not for injection.
Read enclosed leaflet.

Recommended Dosages:
Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

OTHER INFORMATION

Store below 25°C. Protect from light.

Mfg Lic No.:

Distributor:
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks, NSW 2151
Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

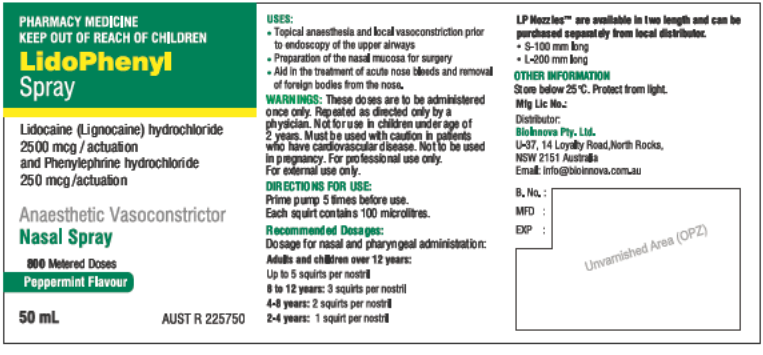
Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT



100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
A new nozzle should be used for each patient to avoid risks of cross infection between patients.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lidocaine **(**lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. 2.5mL Pack: For single use in one patient only. Any unused product should be discarded. 50mL Pack: A New nozzle should be used for each patient to avoid risks of cross infection between patients.

6.5 NATURE AND CONTENTS OF CONTAINER

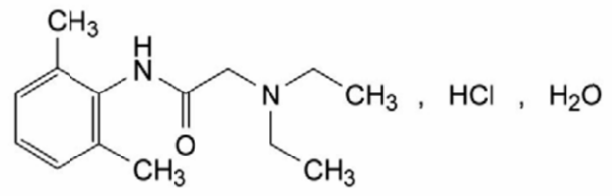
Pump actuated topical solution:
Lidocaine (lignocaine) 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

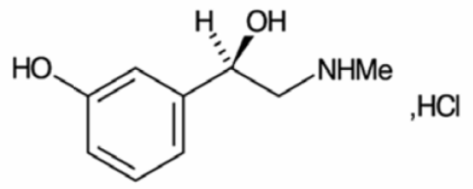
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size

LidoPhenyl spray aerosol (Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v)

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients Lidocaine (lignocaine) hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lidocaine (lignocaine)hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lidocaine (lignocaine)Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lidocaine (lignocaine) the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect you

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of Lidocaine (lignocaine) on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of Lidocaine (lignocaine) (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of Lidocaine (lignocaine) in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

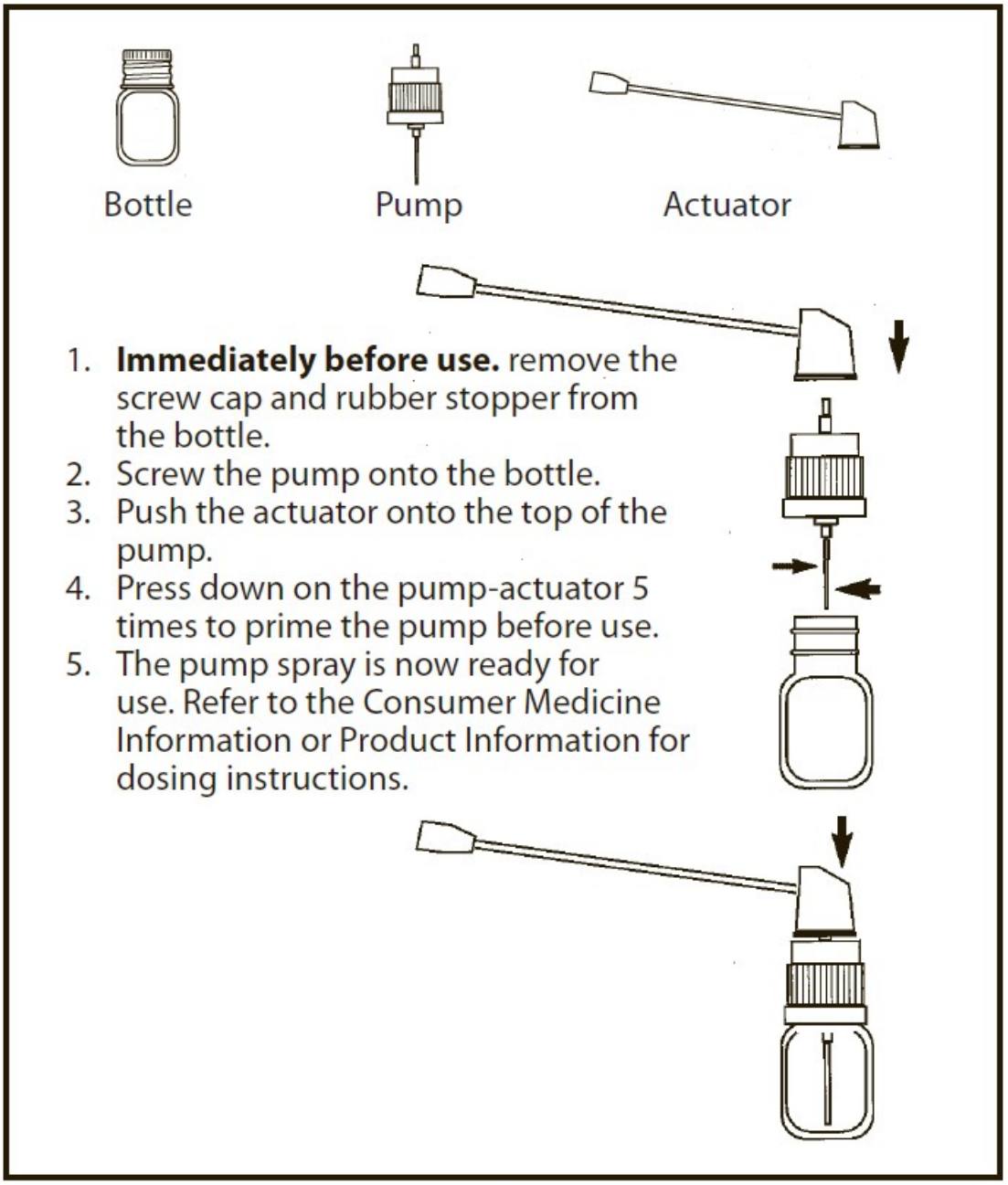
Further information

This leaflet provides only a summary of the information known about Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

This leaflet was prepared September 2019.



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip

A New nozzle should be used for each patient to avoid risks of cross infection between patients.

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

24 March 2020

Re: **Application No:** **OM-2020-GL-02533-1**
Change Codes: **GPI, GDU, QFE**
Application level: **C2**
Variation: **Section 23, Section 9D(3)**

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIDOPHENYL SPRAY bottle
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Initial
Sequence number	0007
Related sequence	0007
Date	2020.03.23
Electronic media	Electronic via eBS portal
Submission size	~ 10 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam

Bioinnova Pty Ltd (ED: 68187) here with submits a variation to update the registered details for the abovementioned products.

Nature and scope of the application:
This application seeks to include following changes:

Change: Increase in excipient quantities for flavour Peppermint water and Sodium Chloride.
Reason: The existing approved quantity of flavour is not sufficient and hence the proposed change is to increase the quanity of flavour in the formulation to make the product palatable.

Change:
Label is revised to rectify the quantities per actuation for active ingredients and quantity of meter dose per pack.

Previous label	Proposed label
Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation and Phenylephrine hydrochloride 250 mcg /actuation	Lidocaine (Lignocaine) hydrochloride 5 mg / actuation and Phenylephrine hydrochloride 0.5 mg /actuation
800 metered dose per 50mL bottle	500 metered dose per 50mL bottle

Reason: Each squirt delivers 100 microlitres and the actual quantities per actuation for active ingredients and quantity of meter dose per pack have been rectifi d to represent the correct quantaties.

Change: Sterility test is removed from the finished product specificati n for 50 mL pack and new microbial tests added for better control.
Also, drug product apprearance is changed to remove t e "steri e solution"
Reason: 50 mL pack was introduced for multiple dose and hence test for sterility is removed.

Supporting documentation:
Attachment 1: Comparative current and propos d formulation
Revised label in Module-1 section 1.3
Revised module-3 section 32P1 f r the proposed formulation
Revised module-3 section 32P51 for he revised finished product specifation

The process validation f r the proposed formulation will be performed before commercialising the produ with the proposed formulation. The process validation batches will be charged on stabili y st dies and TGA will be notified immediately of any batches not meeting specifications through the shelf life.

I trust the nformation provided is satisfactory. However, should you wish to discuss this application please do not hesistate to contact me with the details below.

Fees:
The fees will be paid by electronic bank transfer within 14 days of submission.

Yours sincerely,

s22 [redacted]

s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Attachment-1 Comparative summary of approved and proposed formulation

s47

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019
0003	0002	Supplementary information	Response to request for information	November 2019
0004	0003	Supplementary information	Response to request for information	January 2020
0005	0005	OTC-C2 variation and Notification	Initial	February 2020
0006	0006	Withdrawal of 0005 sequence	Withdrawal	March 2020
0007	0007	OTC-C2 variation	Initial	March 2020

Application General

TGA eBS

Proposed Product name:	LIDOPHENYL SPRAY bottle
Client Name:	Bioinnova Pty Ltd
Sponsor Name:	Bioinnova Pty Ltd
Contact Person:	s22 [redacted]
Contact Telephone:	s22 [redacted]
Contact Facsimile:	
Contact Email:	s22 [redacted]@bioinnova.com.au
This application is to:	Change a current ARTG entry
AUST R:	225750
Submission Cost:	$5,730
Payment Exemption No:	
Application Status:	Passed Validation
Application Type:	C2

CHANGE DETAILS

Change Category:	Formulation changes - excipient ingredients
Change Type:	GPI: Removal and/or addition of a fragrance, flavour, printing ink or colouring agent (if grouping applies), other than change ERT
Assurances:	01) The 'new' goods are intended to replace the existing goods in use. 13) (a) The changeover has been validated* and the sponsor is satisfied that the change will not adversely affect the stability of the product; and (b) Stability testing will continue for the full term of the product's shelf life and the TGA advised immediately of any batches not meeting specifications. *Note: Validation data will be provided during the GMP inspection or upon request by TGA within 3 months following the request. 05) No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process) have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'.
Change Category:	Labelling (including package insert) and product detail changes
Change Type:	GDU: Directions for use - changes to the dosage instructions (if grouping applies), other than changes described in GDS or LIW, where there is no requirement for supporting module 4 and/or module 5 data. For example, changes to the paediatric dosage recommendations for an ibuprofen oral suspension for infants and children 3 months to 12 years to be consistent with the directions in ARGOM's ibuprofen guideline.
Assurances:	01) The 'new' goods are intended to replace the existing goods in use. 03) The only differences between the 'new' goods and the existing goods are related to the indications for use and/or the directions for use.
Change Category:	Quality control changes - finished product specifications
Change Type:	QFE: Finished product specification limits or requirements - less restrictive (except where QFA applies); where any supporting data provided consist only of module 3 (and not module 4) data.
Assurances:	05) No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process) have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'. 27) A copy of the current specification plus a copy of the new specification, with the changes highlighted, have been supplied.
Validation Report:	24-Mar-2020 12:34:00 PM

Failure Messages:
No Failure Messages

Document 18

Other Regulatory Requirements:

The following substance(s) may need to be declared on the label of this medicine. Please refer to the First Schedule/Schedule 1 in Therapeutic Goods Order Nos 69 and 92 for requirements: ethanol (in Concentrated Peppermint Water),sodium chloride

The Manufacturer Macarthys Laboratories Ltd t/a Martindale Pharma is restricted to the manufacture of Registered Therapeutic Good.

The Manufacturer Midas-Care Pharmaceuticals Pvt. Ltd is restricted to the manufacture of Registered Therapeutic Good. Listed Therapeutic Good.

Changes Made:
The Visual identification of Dosage Form has been altered from 'The drug product is a clear, colourless, sterile solution.' to 'The drug product is a clear, bright, colourless solution.'.

s47

[redacted]

With this application, is the sponsor seeking a brand equivalence statement for the purpose of Pharmaceutical Benefits Scheme (PBS) Listing:	No
Is the product intended to replace an existing ARTG entry:	No
Proposed Therapeutic Indications:	1. Preparation of nasal mucosa for surgery or endoscopy. ,2. Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose. ,3. Topical anaesthesia prior to indirect or direct laryngoscopy ,4. Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.
Additional Appliance:	

PRODUCT DETAILS

Dosage Form:	Spray, nasal
Visual Identification of Dosage Form:	The drug product is a clear, bright, colourless solution.
Route of Administration:	Nasal
Container Type:	Bottle

PRODUCT CONTAINER and SHELF LIFE DETAILS

Container Condition:	Closed
Container Closure:	Neither child resistant closure nor restricted flow insert
Proposed Storage Life:	24 Months
Proposed Storage Condition:	Protect from Light
Proposed Storage Temperature:	Store below 25 degrees Celsius
Additional Shelf Life Info:	

PACK SIZE AND POISON SCHEDULE

Pack Size:	2.5 mL
Poison Schedule:	(S2) Pharmacy Medicine

Document 18

Pack Size: 50

Poison Schedule: (S2) Pharmacy Medicine

FORMULATION DETAILS

ACTIVE INGREDIENTS:

STANDARD

Ingredient: lidocaine (lignocaine) hydrochloride monohydrate5 % w/v

Specification:

Animal Origin?: No

Ingredient: phenylephrine.5 % w/v

Specification:

Animal Origin?: No

EXCIPIENT INGREDIENTS:

STANDARD

s47 [redacted]

PROPRIETARY INGREDIENTS

Ingredient: s47 [redacted]

Specification:

MANUFACTURER DETAILS

s47 [redacted]

Document 18

s47

NOZZLE SUPPLY

One LP Nozzle™ is available inside. LP Nozzle™ available separately. A new nozzle should be used for each patient to avoid risks of cross infection between Patients.

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:

ACTIVE INGREDIENT:

Lidocaine (Lignocaine) hydrochloride 5 mg/actuation
and Phenylephrine hydrochloride 0.5 mcg/actuation

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:

These doses are to be administered once only. Repeated as directed only by a physician. Not for use in children under age of 2 years. Must be used with caution in patients who have cardiovascular disease. Not to be used in pregnancy.

For professional use only.
For external use only.
For topical use only.

9 356393 000013

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl™ Spray

Lidocaine (Lignocaine) hydrochloride 5 mg/actuation
and Phenylephrine hydrochloride 0.5 mg/actuation

Anaesthetic Vasoconstrictor
Nasal Spray

500 Metered Doses

Peppermint Flavour

50 mL

AUST R 225750

DIRECTIONS FOR USE:

Prime pump 5 times before use.
Each squirt contains 100 microlitres.
For professional use only.
For topical use only.
Not for injection.
Read enclosed leaflet.

Recommended Dosages:
Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

OTHER INFORMATION

Store below 25°C. Protect from light.

Mfg. Lic. No.: AD/009

Distributor:
BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks, NSW 2151
Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

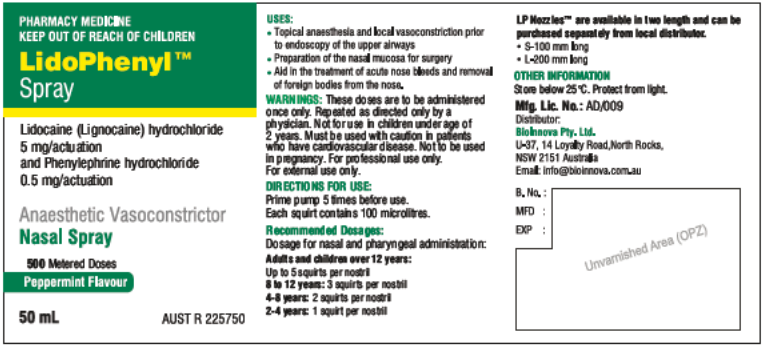
Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT



100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

Module 3: Drug Product

	Lignocaine HCl 5% w/v and Phenylephrine HCl 0.5% w/v Topical Solution

3.2.P.1 Description and Composition of the Drug Product

The drug product is a clear, colourless, solution containing lignocaine hydrochloride 5% w/v and phenylephrine hydrochloride 0.5% w/v in Water for Injections for topical application.

Lignocaine hydrochloride and phenylephrine hydrochloride are established drug substances with well-characterised physicochemical properties.

The composition of the drug product is provided in the following table:

s47

Module 3: Drug Product

	Lignocaine HCl 5% w/v and Phenylephrine HCl 0.5% w/v Topical Solution

3.2.P.5.1 Specification

s47

[redacted]

s47

[redacted]

From: s22
To: s22
Subject: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - deficiencies (C2 application) [SEC=OFFICIAL]
Date: Thursday, 30 April 2020 3:22:44 PM
Attachments: n004445.zip

Hi s22

I hope you are doing well!

Please find attached the revised application as advised.

Please let me know if any amendment is required.

Looking forward to hearing from you.

Thank you once again.

kind regards,
s22
M s22

On Tue, Apr 28, 2020 at 11:57 AM s22 @health.gov.au> wrote:

> Hi s22
>
> Given the specified context in this instance your request for an extension to remedy the application by 30 April 2020 is granted.
>
> You are correct in that you cannot alter the current C2 application online.
>
> Once I receive your response I will alter this application online accordingly and request you verify the changes made to the details of this product before accepting it for evaluation.
>
> Regards
>
> s22
> Professional Officer
> OTC Medicines Evaluation
> Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @bioinnova.com.au>
Sent: Friday, 24 April 2020 11:35 AM
To: s22 @health.gov.au>
Subject: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - deficiencies (C2 application) [SEC=OFFICIAL]

Hi s22

Thank you for your time on call and email.

We will revise the labels, PI/CMI to include "Single-use only" and also will provide a calculation for the correct pump quantity and API quantity per actuation in the label.

We withdraw the proposal to remove the sterility test and revised the specification in this variation.

For a proposal to increase to flavour, we can revise it to 2% from 3%.

As per my understanding, we don't need to submit the application online and we just need to prepare a cover letter and m1 and m3 data to support the proposed variation.

We request you to provide time till 30 April 2020 to resubmit the data.

Many thanks in advance.

Kind regards,

s22

BioInnova Pty Ltd.

M s22

On Thu, Apr 23, 2020 at 1:04 PM s22 @health.gov.au> wrote:

Hi s22

Your application cover letter dated 24 March 2020 refers to proposed changes and a discussion of the deficiencies associated with each change follows:

- Change code: GPI - addition (increase) of flavouring agents (if grouping applies) [C2 – 23]

  ARGOM Appendix 2: Guidelines on quality aspects of OTC applications (Version 1.1, May 2014) on the TGA website states that flavours are normally minor components present **at no more than 2%** in the product formulation. You are proposing to increase the amount of 'Concentrated Peppermint Water' alone from s47 w/v. Module 3 data and justification should be provided to support such a significant/unusual increase for this component of the formulation.

- Change code: GDU - changes to the dosage instructions (if grouping applies) [C2 – 23]

  You state: *"Label is revised to rectify the quantities per actuation for active ingredients and quantity of meter dose per pack".* It would appear this is not a change to the dosage instructions as such, but rather a correction of the ARTG records which would be covered by change code: CTA [C1 – 9D(1)] that requires evidence to support the change. Previous and corrected calculations should also be provided to justify the proposed changes. In addition a consequential change to the product labelling should be covered by change code: LDT – text changes to the label [C2 – 9D(3)].

- Change code: QFE - specification limits or requirements - less restrictive; where any supporting data provided consist only of module 3 [C2 – 9D(3)]

  You state: *"Sterility test is removed from the finished product specification for 50 mL pack and new microbial tests added for better control"* on the basis that *"50 mL pack was introduced for multiple dose and hence test for sterility is removed"*. As previously discussed the 50 mL pack size was approved at that time as a single-use product (i.e. no change to the product labelling or PI document). Consequently the proposed change is unacceptable. Furthermore subsequent text changes to the product labelling and PI to indicate that the product is a multi-use product must revert back to reflect the product is currently approved as a single-use product to be covered by change codes: LDT and DOT (content text changes) [C2 – 9D(3)].

You are strongly encouraged to rework the entire dossier associated with the above C2 application along these lines.

Please advise me when you anticipate such a revised dossier will be provided, which will then be screened for acceptability to evaluate. Approval cannot be considered until the reworked application has been accepted for evaluation.

In the interim a stop clock will be put in place, noting that an extension to respond has already been granted until 28 April 2020.

In regard to your stated intention to remove the sterilisation step from the manufacturing process to facilitate use of the 50 mL pack size as a multi-dose pack, you must acknowledge that this product was evaluated at registration as a sterile, single-use product. Consequently you must consider all consequential changes associated with such a significant change, which may include and is not limited to:

- PMI - Sterility status [C2 – 9D(3)]
- MSD - Deletion of steps of manufacture [CN – 9D(2C)]
- QFE - specification limits or requirements - less restrictive; where any supporting data provided consist only of module 3 [C2 – 9D(3)]
- PSL – new shelf life and in-use shelf life to be established [C2 – 9D(3)]
- LDT and DOT – product labelling and PI content text changes respectively [C2 – 9D(3)]

As discussed such changes should not be included within the scope of the current C2 application, but may be the focus of a separate (new) variation application.

If any clarification is required please call me to discuss.

Regards

s22
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @bioinnova.com.au>
Sent: Wednesday, 22 April 2020 11:41 AM
To: s22 @health.gov.au>
Subject: Re: withdrawal of application for Lidophenyl C2 variation [SEC=OFFICIAL]

Hi s22

Thank you for your call yesterday. We appreciate your concerns regarding sterility of the product and addition of preservative for the multidose pack.

I shared your concerns with our formulation development team and we would like to request you to reconsider your requests.

The subjected product LIDOPHENYL SPRAY bottle doesn't need to be sterile for the intended use hence we would like to remove the sterilization step from the manufacturing process.

Regarding multidose pack, we would like to perform in-use stability study and establish an in-use shelf life for the existing formulation to avoid the addition of a preservative and revision in the formulation. We will include an in-use shelf life on the product label once the in-use shelf life is established for the existing formulation. We assure not to commercialize the product without the in-use

shelf life on the product label.

May we please request to reconsider your requests and approve the proposed variation.

Regards,

s22

BioInnova Pty Ltd

M s22

On Tue, Apr 21, 2020 at 11:48 AM s22 s22 @health.gov.au> wrote:

> Hi s22
>
> Please call me at your earliest convenience to discuss this application.
>
> Regards
>
> s22
> Professional Officer
> OTC Medicines Evaluation
> Complementary and OTC Medicines Branch
>
> Phone: s22 Fax: s22
> Email: s22 @health.gov.au
>
> **Therapeutic Goods Administration**
> Department of Health
> PO Box 100
> Woden ACT 2606 Australia
> www.tga.gov.au
>
> **From:** s22 @bioinnova.com.au>
> **Sent:** Tuesday, 21 April 2020 11:46 AM
> **To:** s22 @health.gov.au>
> **Subject:** withdrawal of application for Lidophenyl C2 variation [SEC=No Protective Marking]

Dear [redacted]

Thank you for your call regarding the C2 variation application for Lidophenyl.

There is no option to withdraw the application from eBS portal.

Could you please advise how to proceed?

Many thanks in advance.

Kind regards,

[redacted]

M [redacted]

BioInnova Pty Ltd

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

30 April 2020

Re: **Application No:** **OM-2020-00259-1**
Change Codes: **GPI, CTA, LDT, DOT**
Application level: **C2, C1 – 9D(1)**
Variation: **Section 23, Section 9D(3)**

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIDOPHENYL SPRAY bottle
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Initial
Sequence number	0008
Related sequence	0008
Date	2020.04.30
Electronic media	Electronic via eBS portal
Submission size	~ 10 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Bioinnova Pty Ltd (EID: 68187) here with submits a variation to update the registered details for the abovementioned products.

Nature and scope of the application:
This application seeks to include following changes:

Change: Increase in excipient quantities for flavour Peppermint water and Sodium Chloride.
Reason: The existing approved quantity of flavour is not sufficient and hence the proposed change is to increase the quanity of flavour in the formulation to make the product palatable.

Change:
Label is revised to rectify the quantities per actuation for active ingredients and quantity of meter dose per pack.

Previous label	**Proposed label**
Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation and Phenylephrine hydrochloride 250 mcg /actuation	Lidocaine (Lignocaine) hydrochloride 5 mg / actuation and Phenylephrine hydrochloride 0.5 mg /actuation
800 metered dose per 50mL bottle	480 metered dose per 50mL bottle
Each squirt contains 100 microlitres	Each squirt contains 100 microlitres

Reason: Previously the metered dose was calculated based on 50 microleters for each actuation by error. This should have been calcluated based on 100 microleters for each actuation.

Theoretical calculation based on 50 microliters per actuation:
Each squirt delivers 50 microlitres (50 mcl means 0.05ml)
so 1 ml = 20 dosage & 50 ml = 1000 Dosage.
Hence, 800 metered dose per 50mL bottle was claimed.

Each mL contains Lidocaine (Lignocaine) hydrochloride 50 mg and 5 mg Phenylephrine hydrochloride hence calculation as per 50 microliters per actuation:

Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation
and Phenylephrine hydrochloride 250 mcg /actuation

Theoretical calculation based on 100 microliters per actuation:

Each squirt delivers 100 microlitres (100 mcl means 0.1ml)
so 1 ml = 10 dosage & 50 ml = 500 Dosage.

Actually each squirt delivers 100 microlitres ± 10% based on supplier COA.

Practically we found:

Sample	**Average dose delivery (35 Spray)**	**Tentative Number of Doses/50 ml Bottle**
1	104.90 mg	480
2	103.83 mg	493

Hence we propose to claim not less than 480 metered doses.

Each mL contains Lidocaine (Lignocaine) hydrochloride 50 mg and 5 mg Phenylephrine hydrochloride hence calculation as per 100 microliters per actuation:

Lidocaine (Lignocaine) hydrochloride 5000 mcg / actuation i.e. 5 mg / actuation
and Phenylephrine hydrochloride 500 mcg /actuation i.e. 0.5 mg / actuation

Label and PI is also changed to state "For single use only".

Supporting documentation:
Attachment 1: Comparative current and proposed formulation
Revised label in Module-1 section 1.3
Revised module-3 section 32P1 for the proposed formulation

I trust the information provided is satisfactory. However, should you wish to discuss this application please do not hesistate to contact me with the details below.

Fees:
The fees will be paid by electronic bank transfer within 14 days of submission.

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Attachment-1 Comparative summary of approved and proposed formulation

s47

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019
0003	0002	Supplementary information	Response to request for information	November 2019
0004	0003	Supplementary information	Response to request for information	January 2020
0005	0005	OTC-C2 variation and Notification	Initial	February 2020
0006	0006	Withdrawal of 0005 sequence	Withdrawal	March 2020
0007	0007	OTC-C2 variation	Initial	March 2020
0008	0008	Supplementary information	Response to request for information	April 2020

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

30 April 2020

Re: **Application No:** **OM-2020-00259-1**
Change Codes: **GPI, CTA, LDT, DOT**
Application level: **C2, C1 – 9D(1)**
Variation: **Section 23, Section 9D(3)**

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIDOPHENYL SPRAY bottle
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Initial
Sequence number	0008
Related sequence	0008
Date	2020.04.30
Electronic media	Electronic via eBS portal
Submission size	~ 10 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Bioinnova Pty Ltd (EID: 68187) here with submits a variation to update the registered details for the abovementioned products.

Nature and scope of the application:
This application seeks to include following changes:

Change: Increase in excipient quantities for flavour Peppermint water and Sodium Chloride.
Reason: The existing approved quantity of flavour is not sufficient and hence the proposed change is to increase the quanity of flavour in the formulation to make the product palatable.

Change:
Label is revised to rectify the quantities per actuation for active ingredients and quantity of meter dose per pack.

Previous label	**Proposed label**
Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation and Phenylephrine hydrochloride 250 mcg /actuation	Lidocaine (Lignocaine) hydrochloride 5 mg / actuation and Phenylephrine hydrochloride 0.5 mg /actuation
800 metered dose per 50mL bottle	480 metered dose per 50mL bottle
Each squirt contains 100 microlitres	Each squirt contains 100 microlitres

Reason: Previously the metered dose was calculated based on 50 microleters for each actuation by error. This should have been calcluated based on 100 microleters for each actuation.

Theoretical calculation based on 50 microliters per actuation:
Each squirt delivers 50 microlitres (50 mcl means 0.05ml)
so 1 ml = 20 dosage & 50 ml = 1000 Dosage.
Hence, 800 metered dose per 50mL bottle was claimed.

Each mL contains Lidocaine (Lignocaine) hydrochloride 50 mg and 5 mg Phenylephrine hydrochloride hence calculation as per 50 microliters per actuation:

Lidocaine (Lignocaine) hydrochloride 2500 mcg / actuation
and Phenylephrine hydrochloride 250 mcg /actuation

Theoretical calculation based on 100 microliters per actuation:

Each squirt delivers 100 microlitres (100 mcl means 0.1ml)
so 1 ml = 10 dosage & 50 ml = 500 Dosage.

Actually each squirt delivers 100 microlitres ± 10% based on supplier COA.

Practically we found:

Sample	**Average dose delivery (35 Spray)**	**Tentative Number of Doses/50 ml Bottle**
1	104.90 mg	480
2	103.83 mg	493

Hence we propose to claim not less than 480 metered doses.

Each mL contains Lidocaine (Lignocaine) hydrochloride 50 mg and 5 mg Phenylephrine hydrochloride hence calculation as per 100 microliters per actuation:

Lidocaine (Lignocaine) hydrochloride 5000 mcg / actuation i.e. 5 mg / actuation
and Phenylephrine hydrochloride 500 mcg /actuation i.e. 0.5 mg / actuation

Label and PI is also changed to state "For single use only".

Supporting documentation:
Attachment 1: Comparative current and proposed formulation
Revised label in Module-1 section 1.3
Revised module-3 section 32P1 for the proposed formulation

I trust the information provided is satisfactory. However, should you wish to discuss this application please do not hesistate to contact me with the details below.

Fees:
The fees will be paid by electronic bank transfer within 14 days of submission.

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lidocaine **(**lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

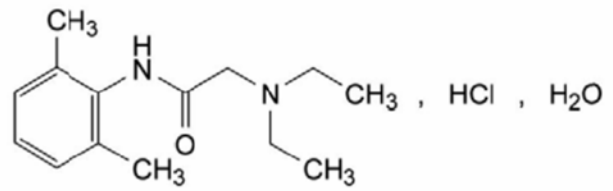
Pump actuated topical solution:
Lidocaine (lignocaine) 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

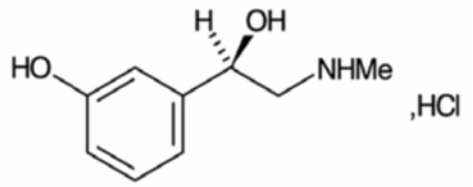
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 4.2	Removed text on nozzle.

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.
~~A new nozzle should be used for each patient to avoid risks of cross infection between patients.~~

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lidocaine **(**lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. ~~2.5mL Pack:~~ For single use in one patient only. Any unused product should be discarded. ~~50mL Pack: A New nozzle should be used for each patient to avoid risks of cross infection between patients.~~

6.5 NATURE AND CONTENTS OF CONTAINER

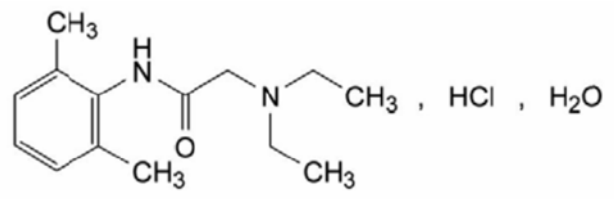
Pump actuated topical solution:
Lidocaine (lignocaine) 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

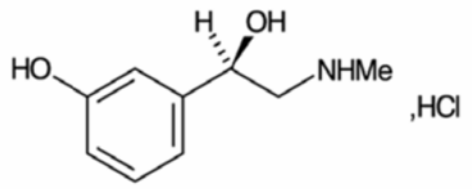
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 4.2	Removed text on nozzle.

LidoPhenyl spray aerosol (Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v)

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients Lidocaine (lignocaine) hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lidocaine (lignocaine)hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lidocaine (lignocaine)Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lidocaine (lignocaine) the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of Lidocaine (lignocaine) on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of Lidocaine (lignocaine) (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of Lidocaine (lignocaine) in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

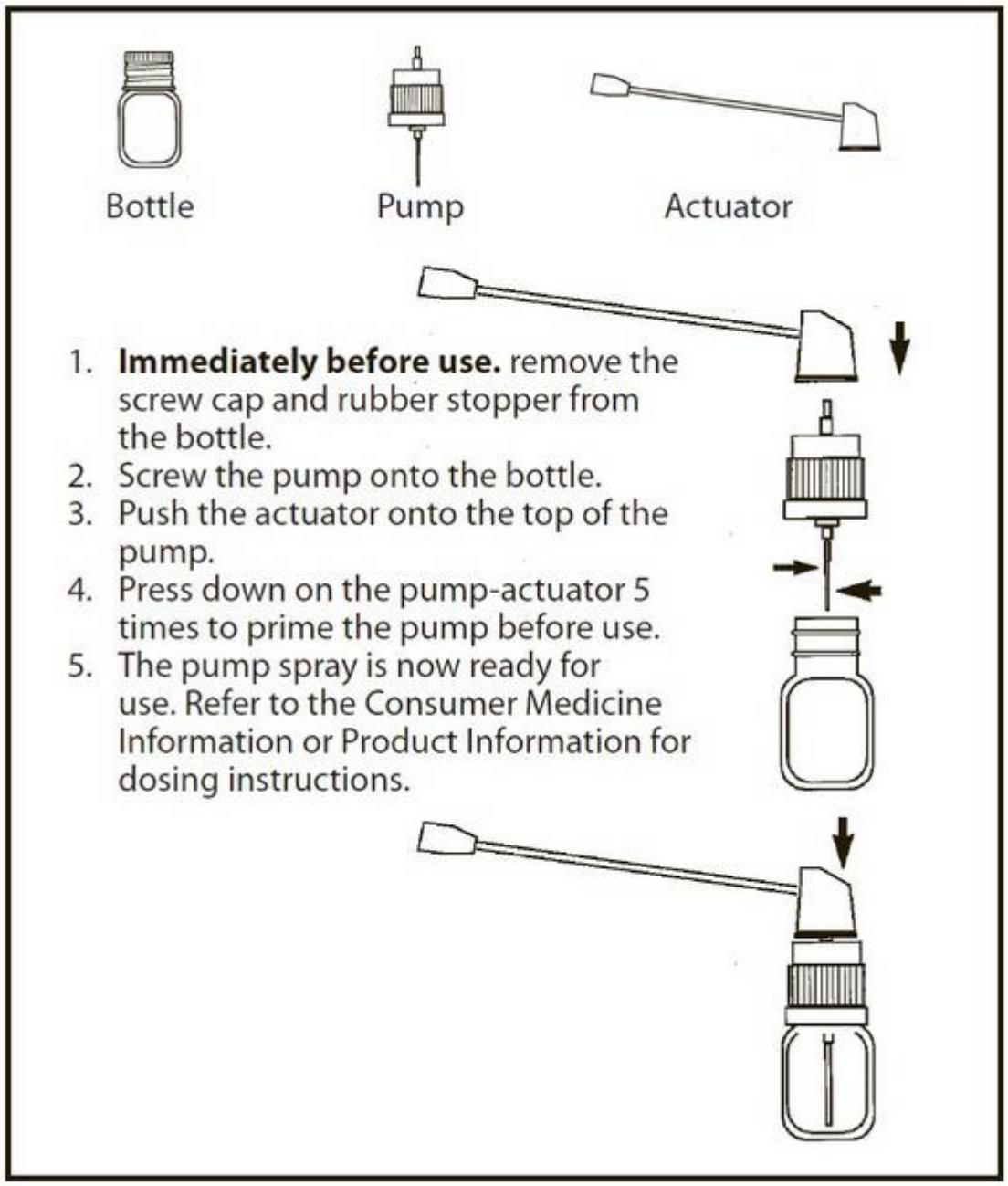
Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

This leaflet was prepared April 2020.

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip. The product is sterile until opened, and contains no preservatives. Use once in one patient only and discard the bottle and any remaining solution in an appropriate

manner.

LidoPhenyl spray aerosol (Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v)

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients Lidocaine (lignocaine) hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lidocaine (lignocaine)hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lidocaine (lignocaine)Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lidocaine (lignocaine) the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of Lidocaine (lignocaine) on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of Lidocaine (lignocaine) (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of Lidocaine (lignocaine) in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

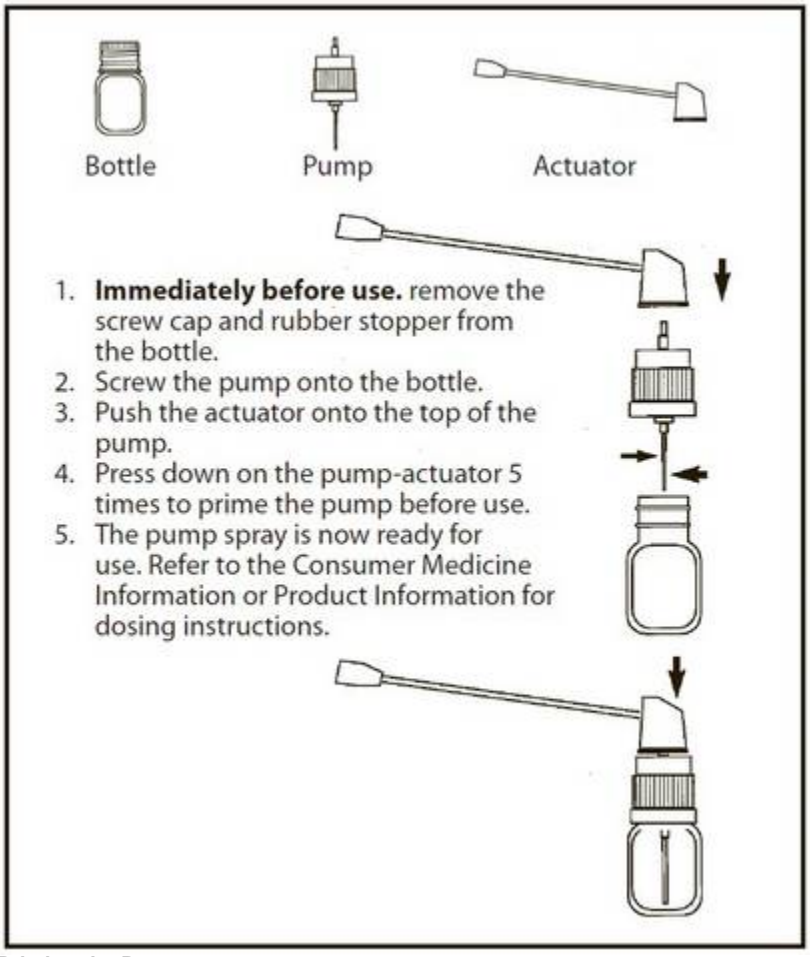
Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

This leaflet was prepared ~~September~~ April 2020.~~2019.~~

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip. The product is sterile until opened, and contains no preservatives. Use once in one patient only and discard the bottle and any remaining solution in an appropriate

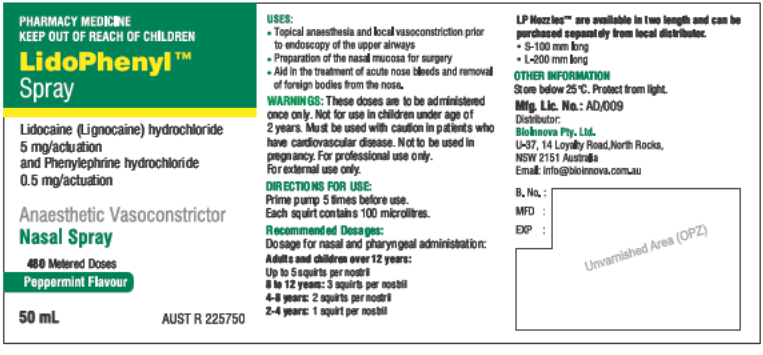
manner.

~~A New nozzle should be used for each patient to avoid risks of cross infection between patients.~~

Formatted: Right: 1.76 cm, Space Before: 0.05 pt

Formatted: Font: (Default) Arial, 11 pt, English (United States)

Formatted: Body Text, Indent: Left: 0.39 cm, Right: 1.76 cm, Space Before: 0.05 pt, Not Don't swap indents on facing pages



100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

NOZZLE SUPPLY

One LP Nozzle™ is available inside. LP Nozzle™ available separately.

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:

ACTIVE INGREDIENT:

Lidocaine (Lignocaine) hydrochloride 5 mg/actuation
and Phenylephrine hydrochloride 0.5 mg/actuation

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:

These doses are to be administered once only.
Not for use in children under age of 2 years. Must be used with caution in patients who have cardiovascular disease. Not to be used in pregnancy.

For professional use only.
For external use only.
For topical use only.

9 356393 000013

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl™ Spray

Lidocaine (Lignocaine) hydrochloride 5 mg/actuation
and Phenylephrine hydrochloride 0.5 mg/actuation

Anaesthetic Vasoconstrictor
Nasal Spray

480
Metered Doses

Peppermint Flavour

For Single use only.
50 mL

AUST R 225750

DIRECTIONS FOR USE:

Prime pump 5 times before use.
Each squirt contains 100 microlitres.

For professional use only. For topical use only. Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner. Not for injection.
Read enclosed leaflet.

Recommended Dosages:

Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

OTHER INFORMATION

Store below 25°C. Protect from light.
Mfg. Lic. No.: AD/009
Distributor:
BioInnova Pty Ltd
U-37, 14 Loyalty Road, North Rocks, NSW 2151 Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT

Module 3: Drug Product

	Lignocaine HCl 5% w/v and Phenylephrine HCl 0.5% w/v Topical Solution

3.2.P.1 Description and Composition of the Drug Product

The drug product is a clear, colourless, solution containing lignocaine hydrochloride 5% w/v and phenylephrine hydrochloride 0.5% w/v in Water for Injections for topical application.

Lignocaine hydrochloride and phenylephrine hydrochloride are established drug substances with well-characterised physicochemical properties.

The composition of the drug product is provided in the following table:

s47

From: s22
To: s22
Subject: Re: TRIM: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - deficiencies (C2 application) [SEC=OFFICIAL]
Date: Tuesday, 12 May 2020 12:17:21 PM
Attachments: image001.png [1]
32p1-desc-comp.pdf [2]
Formulation comparison.pdf [3]
carton-annotated.pdf [4]
label-annotated.pdf [5]

Hi s22

Please find attached updated documents as requested.

Ingredients	Qty from	Qty to	Unit
Lignocaine Hydrochloride	s47		
Phenylephrine Hydrochloride			
Dilute Hydrochloric Acid			
Sodium Hydroxide			
Water for Injections			
Stevia rebaudiana			
Concentrated Peppermint Water			
Acesulfame Potassium			
Sodium Chloride			

Earlier there was an error in converting Sodium chloride from mg/ml to %w/v.

Please advise if you need any further information. Please advise if you need revised documents as a NeeS.

Thank you very much.

Kind regards,
s22

> Hi s22
>
> As discussed today, please provide at your earliest convenience a replacement 'Comparative summary of approved and proposed formulation' table ensuring that ingredient proportions and units (mg/mL or mg/L or mL/mL to % w/v or % v/v) are accurate and consistent with the current ARTG records as follows:

Summary of Comments on Document 20.PDF

Page: 1

Number: 1 Author: Date: Indeterminate

Number: 2 Author: Date: Indeterminate

Number: 3 Author: Date: Indeterminate

Number: 4 Author: Date: Indeterminate

Number: 5 Author: Date: Indeterminate

If any correction are required to these current ARTG records please provide appropriate justification.

If any clarification is required please call me to discuss.

Regards

s22
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @bioinnova.com.au>
Sent: Thursday, 30 April 2020 3:19 PM
To: s22 @health.gov.au>
Subject: TRIM: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - deficiencies (C2 application) [SEC=OFFICIAL]

Hi s22

I hope you are doing well!

Please find attached the revised application as advised.

Please let me know if any amendment is required.

Looking forward to hearing from you.

Thank you once again.

kind regards,

s22

M s22

On Tue, Apr 28, 2020 at 11:57 AM s22 @health.gov.au> wrote:

> Hi s22
>
> Given the specified context in this instance your request for an extension to remedy the application by 30 April 2020 is granted.
>
> You are correct in that you cannot alter the current C2 application online.
>
> Once I receive your response I will alter this application online accordingly and request you verify the changes made to the details of this product before accepting it for evaluation.
>
> Regards
>
> s22
> Professional Officer
> OTC Medicines Evaluation
> Complementary and OTC Medicines Branch
>
> Phone: s22 Fax: s22
> Email: s22 @health.gov.au
>
> **Therapeutic Goods Administration**
> Department of Health
> PO Box 100
> Woden ACT 2606 Australia
> www.tga.gov.au

From: s22 @bioinnova.com.au>
Sent: Friday, 24 April 2020 11:35 AM
To: s22 @health.gov.au>
Subject: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - deficiencies (C2 application) [SEC=OFFICIAL]

Hi s22

Thank you for your time on call and email.

We will revise the labels, PI/CMI to include "Single-use only" and also will provide a calculation for the correct pump quantity and API quantity per actuation in the label.

We withdraw the proposal to remove the sterility test and revised the specification in this variation.

For a proposal to increase to flavour, we can revise it s47

As per my understanding, we don't need to submit the application online and we just need to prepare a cover letter and m1 and m3 data to support the proposed variation.

We request you to provide time till 30 April 2020 to resubmit the data.

Many thanks in advance.

Kind regards,

s22

BioInnova Pty Ltd.

M s22

On Thu, Apr 23, 2020 at 1:04 PM s22 @health.gov.au> wrote:

> Hi s22

Your application cover letter dated 24 March 2020 refers to proposed changes and a discussion of the deficiencies associated with each change follows:

- Change code: GPI - addition (increase) of flavouring agents (if grouping applies) [C2 – 23]

  ARGOM Appendix 2: Guidelines on quality aspects of OTC applications (Version 1.1, May 2014) on the TGA website states that flavours are normally minor components present **at no more than 2%** in the product formulation. You are proposing to increase the amount of 'Concentrated Peppermint Water' alone from s47 [redacted] Module 3 data and justification should be provided to support such a significant/unusual increase for this component of the formulation.

- Change code: GDU - changes to the dosage instructions (if grouping applies) [C2 – 23]

  You state: *"Label is revised to rectify the quantities per actuation for active ingredients and quantity of meter dose per pack"*. It would appear this is not a change to the dosage instructions as such, but rather a correction of the ARTG records which would be covered by change code: CTA [C1 – 9D(1)] that requires evidence to support the change. Previous and corrected calculations should also be provided to justify the proposed changes. In addition a consequential change to the product labelling should be covered by change code: LDT – text changes to the label [C2 – 9D(3)].

- Change code: QFE - specification limits or requirements - less restrictive; where any supporting data provided consist only of module 3 [C2 – 9D(3)]

  You state: *"Sterility test is removed from the finished product specification for 50 mL pack and new microbial tests added for better control"* on the basis that *"50 mL pack was introduced for multiple dose and hence test for sterility is removed"*. As previously discussed the 50 mL pack size was approved at that time as a single-use product (i.e. no change to the product labelling or PI document). Consequently the proposed change is unacceptable. Furthermore subsequent text changes to the product labelling and PI to indicate that the product is a multi-use product must revert back to reflect the product is currently approved as a single-use product to be covered by change codes: LDT and DOT (content text changes) [C2 – 9D(3)].

You are strongly encouraged to rework the entire dossier associated with the above C2 application along these lines.

Please advise me when you anticipate such a revised dossier will be provided, which will then be screened for acceptability to evaluate. Approval cannot be considered until the reworked application has been accepted for evaluation.

In the interim a stop clock will be put in place, noting that an extension to respond has already been granted until 28 April 2020.

In regard to your stated intention to remove the sterilisation step from the manufacturing process to facilitate use of the 50 mL pack size as a multi-dose pack, you must acknowledge that this product was evaluated at registration as a sterile, single-use product. Consequently you must consider all consequential changes associated with such a significant change, which may include and is not limited to:

- PMI - Sterility status [C2 – 9D(3)]
- MSD - Deletion of steps of manufacture [CN – 9D(2C)]
- QFE - specification limits or requirements - less restrictive; where any supporting data provided consist only of module 3 [C2 – 9D(3)]
- PSL – new shelf life and in-use shelf life to be established [C2 – 9D(3)]
- LDT and DOT – product labelling and PI content text changes respectively [C2 – 9D(3)]

As discussed such changes should not be included within the scope of the current C2 application, but may be the focus of a separate (new) variation application.

If any clarification is required please call me to discuss.

Regards

s22
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @bioinnova.com.au>
Sent: Wednesday, 22 April 2020 11:41 AM
To: s22 @health.gov.au>
Subject: Re: withdrawal of application for Lidophenyl C2 variation [SEC=OFFICIAL]

Hi s22

Thank you for your call yesterday. We appreciate your concerns regarding sterility of the product and addition of preservative for the multidose pack.

I shared your concerns with our formulation development team and we would like to request you to reconsider your requests.

The subjected product LIDOPHENYL SPRAY bottle doesn't need to be sterile for the intended use hence we would like to remove the sterilization step from the manufacturing process.

Regarding multidose pack, we would like to perform in-use stability study and establish an in-use shelf life for the existing formulation to avoid the addition of a preservative and revision in the formulation. We will include an in-use shelf life on the product label once the in-use shelf life is established for the existing formulation. We assure not to commercialize the product

without the in-use shelf life on the product label.

May we please request to reconsider your requests and approve the proposed variation.

Regards,

s22

BioInnova Pty Ltd

M s22

On Tue, Apr 21, 2020 at 11:48 AM s22 @health.gov.au> wrote:

Hi s22

Please call me at your earliest convenience to discuss this application.

Regards

s22
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 @bioinnova.com.au>
Sent: Tuesday, 21 April 2020 11:46 AM
To: s22 @health.gov.au>
Subject: withdrawal of application for Lidophenyl C2 variation [SEC=No Protective Marking]

Dear s22

Thank you for your call regarding the C2 variation application for Lidophenyl.

There is no option to withdraw the application from eBS portal.

Could you please advise how to proceed?

Many thanks in advance.

Kind regards,

s22 [redacted]

M s22 [redacted]

BioInnova Pty Ltd

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Module 3: Drug Product

	Lignocaine HCl 5% w/v and Phenylephrine HCl 0.5% w/v Topical Solution

3.2.P.1 Description and Composition of the Drug Product

The drug product is a clear, colourless, solution containing lignocaine hydrochloride 5% w/v and phenylephrine hydrochloride 0.5% w/v in Water for Injections for topical application.

Lignocaine hydrochloride and phenylephrine hydrochloride are established drug substances with well-characterised physicochemical properties.

The composition of the drug product is provided in the following table:

s47

s47

[redacted]

Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT

Page: 11

Number: 1 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:58:01 PM +10'00'

included Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner

Number: 2 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:53:08 PM +10'00'

Corrected to
Lidocaine (Lignocaine) hydrochloride 5 mg/actuation and Phenylephrine hydrochloride 0.5 mg/actuation

Number: 3 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:53:06 PM +10'00'

Corrected to
Lidocaine (Lignocaine) hydrochloride 5 mg/actuation and Phenylephrine hydrochloride 0.5 mg/actuation

Number: 4 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:56:48 PM +10'00'

removed A new nozzle should be used for each patient to avoid risks of cross infection between Patients

Number: 5 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:56:03 PM +10'00'

Removed Repeated as directed by physician.

Number: 6 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:57:12 PM +10'00'

480

Number: 7 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:57:28 PM +10'00'

For Single use only.

Document 20

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl
Spray

2

Lidocaine (Lig[illegible]) hydrochloride
2500 mcg / a[illegible]
and Phenylep[illegible]rochloride
250 mcg /actuation

Anaesthetic Vasoconstrictor
Nasal Spray 3

8[illegible]ed Doses
P[illegible]t 4 avour

5 [illegible] mL

AUST R 225750

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper airways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose. 1

WARNINGS: The [illegible]re to be administered once only. Repea[illegible]cted only by a physician. Not fo[illegible]ldren under age of 2 years. Must be [illegible] caution in patients who have cardiovascular disease. Not to be used in pregnancy. For professional use only.
For external use only.

DIRECTIONS FOR USE:
Prime pump 5 times before use.
Each squirt contains 100 microlitres.

Recommended Dosages:
Dosage for nasal and pharyngeal administration:
Adults and children over 12 years:
Up to 5 squirts per nostril
8 to 12 years: 3 squirts per nostril
4-8 years: 2 squirts per nostril
2-4 years: 1 squirt per nostril

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

OTHER INFORMATION
Store below 25°C. Protect from light.
Mfg Lic No.:
Distributor:
BioInnova Pty. Ltd.
U-37, 14 Loyalty Road,North Rocks,
NSW 2151 Australia
Email: info@bioinnova.com.au

B. No. :
MFD :
EXP :

Unvarnished Area (OPZ)

100 MM X 45 MM

s47 [redacted]

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

Page: 12

Number: 1 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 1:00:59 PM +10'00'
Removed Repeated as directed by physician.

Number: 2 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 12:59:45 PM +10'00'
Corrected as
Lidocaine (Lignocaine) hydrochloride
5 mg/actuation
and Phenylephrine hydrochloride
0.5 mg/actuation

Number: 3 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 1:00:03 PM +10'00'
480

Number: 4 Author: Seed Pharma Subject: Sticky Note Date: 12/05/2020 1:00:43 PM +10'00'
For Single use only

From: s22 [redacted]
To: s22 [redacted]
Cc: eSubmissions
Subject: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of screening - minor deficiencies (C2 application) [SEC=OFFICIAL]
Date: Friday, 15 May 2020 7:47:12 PM
Attachments: n004445.zip

Dear s22 [redacted]

Please find an enclosed response for the application OM-2020-00259-1 sequence no 0009.

Product: LidoPhenyl Spray
NeeS no : n004445
Client Name: BioInnova Pty Ltd

Please feel free to contact me if you need any further information.

Thank you.

Regards,
s22 [redacted]
BioInnova Pty Ltd
M s22 [redacted]

On Wed, May 13, 2020 at 12:21 PM s22 [redacted] @health.gov.au> wrote:

> I refer to your applications seeking approval to change the above products (Submission ID: OM-2020-00259-1, File: 2013/014736).
>
> Your application and the supporting information in the application dossier have been screened to verify that it meets the requirements for requests to vary a medicine under sections 23 and 9D of the Act.
>
> Applications that do not meet the requirements will not be accepted for evaluation. However, where there are deficiencies or omissions, the applicant is given five working days to remedy the application.
>
> Your application has been identified as omitting some required information. In order to rectify the deficiency, please address the following issues **within five working days (due date: 20 May 2020).**
>
> Please provide your response by email to s22 [redacted] @health.gov.au.
>
> **If your registration application was submitted in eCTD (or NeeS) format (i.e. with an e—identifier / sequence number), please ensure that**

- **all responses to queries; and**
- **all subsequent change applications**

continue to be in eCTD (or NeeS) format. In this case, responses to queries should also be copied to eSubmissions@health.gov.au .

If these deficiencies/omissions are not rectified before the due date, the application cannot be accepted for evaluation and will be removed from the application lodgement system in TGA eBusiness Services. Application fees cannot be refunded.

For further information on the application process and the requirements for an effective application, please refer to:

- ARGOM
- Process to change a registered OTC medicine
- *General dossier requirements*
- *Common Technical Document Module 1: OTC medicines*
- *Mandatory requirements for an effective over-the-counter medicines application*

Please contact me if you require further clarification of these matters.

Regards

s22 [redacted]
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 [redacted] Fax: s22 [redacted]
Email: s22 [redacted] @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

MATTERS TO BE ADDRESSED

1. Please provide a clean PDF version of the proposed PI which has been electronically bookmarked showing the first, second and third level subheadings.

2. You have only provided the 50 mL pack size product labelling and have advised that the registered 2.5 mL pack size has not yet been marketed. Consequently you should provide an assurance that a variation application to bring the product labelling of the 2.5 mL pack size into full compliance with TGO 92 will be submitted and must be approved by the TGA prior to supplying and marketing this pack size in Australia.

3. The corresponding eBS application has now been amended to include appropriate change codes, revert the sterility status (including visual identification of dosage form) and correct ingredient proportions and units. Consequently ‘sponsor verification’ of your application is required:

Please ensure that you verify the application details included in this application.

Please check your application carefully.

To verify the application details, click on the "View submissions" link on the TGA Business Services homepage.

Click the 'down arrow' on the left hand side of the product listing, then click "Print Preview". This will show the original application and TGA revised application on the same screen.

After reviewing, click "Continue” (top left, under “I agree with the changes:”). This will open the Declaration page. Click “Agree”

Please let me know by return email once you have verified the application.

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

14 May 2020

Re: Response to the OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of screening - minor deficiencies (C2 application)

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIDOPHENYL SPRAY bottle
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Supplementary information
Sequence number	0009
Related sequence	0008
Date	2020.05.14
Electronic media	Electronic via eBS portal
Submission size	~ 2 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Bioinnova Pty Ltd (EID: 68187) here with submits response to the outcome of screening - minor deficiencies (C2 application).

I trust the information provided is satisfactory. However, should you wish to discuss this application please do not hesistate to contact me with the details below.

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019
0003	0002	Supplementary information	Response to request for information	November 2019
0004	0003	Supplementary information	Response to request for information	January 2020
0005	0005	OTC-C2 variation and Notification	Initial	February 2020
0006	0006	Withdrawal of 0005 sequence	Withdrawal	March 2020
0007	0007	OTC-C2 variation	Initial	March 2020
0008	0008	Supplementary information	Response to request for information	April 2020
0009	0008	Supplementary information	Response to request for information	May 2020

OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of screening - minor deficiencies (C2 application)

Question:1
Please provide a clean PDF version of the proposed PI which has been electronically bookmarked showing the first, second and third level subheadings.

Response:1
We acknowledge the comment. Electronically bookmarked PI is enclosed in M1 Section 131.

Question:2
You have only provided the 50 mL pack size product labelling and have advised that the registered 2.5 mL pack size has not yet been marketed. Consequently you should provide an assurance that a variation application to bring the product labelling of the 2.5 mL pack size into full compliance with TGO 92 will be submitted and must be approved by the TGA prior to supplying and marketing this pack size in Australia.

Response:2
We confirm that we have no plans to market the 2.5 mL pack size. However, we provide the assurance that if we plan to market the 2.5mL pack size, we will submit variation application to bring the product labelling of the 2.5 mL pack size into full compliance with TGO 92 prior to supplying and marketing this pack size in Australia.

Question:3
The corresponding eBS application has now been amended to include appropriate change codes, revert the sterility status (including visual identification of dosage form) and correct ingredient proportions and units. Consequently 'sponsor verification' of your application is required:

Response:3
We acknowledge the comment and We have accepted the changes proposed in the application.

AUSTRALIAN PRODUCT INFORMATION – LidoPhenyl Spray

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

It contains Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Topical solution, Pump actuated

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril. Each squirt measures 100 microlitres.

Method of administration

Route of administration: nasal or pharyngeal.
Do not exceed the recommended dosage regimens.
Do not administer to children under 2 years of age.
Doses are to be administered once only.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

No data available.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Australian Pregnancy Categorisation: **Category B2-** Lidocaine **(**lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.

6.5 NATURE AND CONTENTS OF CONTAINER

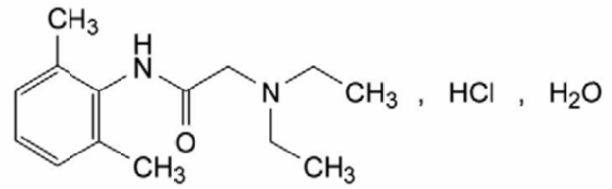
Pump actuated topical solution:
Lidocaine (lignocaine) 5 mg, phenylephrine 0.5 mg)/spray
2.5 mL and 50 mL

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

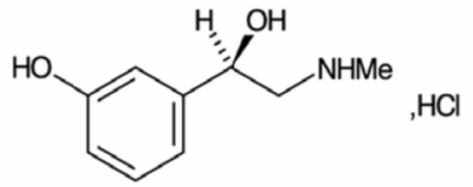
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 4.2	Removed text on nozzle.

From: s22
To: s22 ; eSubmissions
Subject: Re: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of evaluation - request for information [SEC=OFFICIAL]
Date: Thursday, 18 June 2020 9:20:12 PM
Attachments: image001.png
n004445.zip

Dear s22 and eSubmissions,

Please find enclosed a response to the OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of evaluation - request for information.
NeeS submission number: n004445
Sequence Number: 0009

Also, I have verified the application form on eBS.

Thank you.

Kind regards
s22
M 0s22

On Thu, Jun 4, 2020 at 11:12 AM s22 @health.gov.au> wrote:

> OUTCOME OF EVALUATION
>
> The evaluation of your application is now complete and a request for information is required to progress this application.
>
> Please provide a response by return email to each of the recommendations itemised below, with supporting documentation, **by COB 26 June 2020**.
>
> 1. As per TGO 92 s.8(2)(b), it would appear the proposed critical health information (CHI) on the primary pack (carton) label does not present the appropriate headings in the mandatory order due to:
>
> - the CHI being split over two panels which are not adjacent, and
>
> - there is no indication that the CHI continues from the first to the second panel [see 'Medicine labels - Guidance on TGO 91 and TGO 92' (Version 2.1, July 2019)].
>
> To rectify this situation the following battery of revision is recommended:
>
> - The carton labelling should be reformatted such that the two panels upon which the CHI is located are adjacent to each other from left (first panel) to right (second panel);

- Place the word ‘continued…’ at the right bottom corner of the first panel and use an arrow head (⊳) at the end of ‘continued…’ to mark the direction of the continuation; and

- Title the subsequent panel ‘MEDICINE INFORMATION (continued)’.

2. To improve comprehension and readability it is suggested that the information under the heading: ‘WARNINGS’ of the CHI on the primary pack (carton) label be reworked and reformatted as follows:

   WARNINGS:

   Not for use in children under 2 years of age or during pregnancy.

   Must be used with caution in patients who have cardiovascular disease.

   For professional use only.

   For external use only.

   For topical use only.

   Not for injection.

3. As per TGO 92 s.8(2), the bar code under the heading: ‘WARNINGS’ must be relocated outside of the CHI on the primary pack (carton) label.

4. To improve comprehension and readability it is suggested that the information under the heading: ‘DIRECTIONS FOR USE’ of the CHI on the primary pack (carton) label be reworked and reformatted as follows:

   DIRECTIONS FOR USE:

   Prime pump 5 times before use.

   Each squirt contains 100 microlitres.

   Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner.

   Read enclosed leaflet before use.

   Doses are to be administered once only.

   Dosage for nasal and pharyngeal administration:

5. As per TGO 92 s.8(2)(e), the information: *"Mfg. Lic. No.: AD/009"* under the heading: 'OTHER INFORMATION' must be relocated outside of the CHI on the primary pack (carton) label.

6. For consistency, these suggested changes to the primary pack (carton) label may also be applied appropriately to the container (bottle) label.

7. The sponsor should provide an assurance that the batch number of the medicine preceded by the batch number prefix and the expiry date of the medicine preceded by the expiry date prefix will be displayed on the primary pack (carton) labelling.

8. The sponsor should refer to the *Form for providing product information* on the TGA website (https://www.tga.gov.au/reformatting-product-information-frequently-asked-questions) and make the following revisions to the revised and reformatted PI:

    - The title of the document should be revised to: 'AUSTRALIAN PRODUCT INFORMATION – LIDOPHENYL SPRAY (Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride)'.

    - The information in Section 2: 'QUALITATIVE AND QUANTITATIVE COMPOSITION' should be revised to: 'Lidocaine (lignocaine) hydrochloride 5 mg/actuation (5% w/v) and Phenylephrine hydrochloride 0.5 mg/actuation (0.5% w/v). This product does not contain any antimicrobial agent. For the full list of excipients, see Section 6.1 List of excipients'.

    - The information in Section 3: 'PHARMACEUTICAL FORM' should be revised to: 'Pump actuated topical nasal spray which is a clear, colourless, sterile solution and should not be used if it is coloured'.

    - The information in Section 4.2: 'DOSE AND METHOD OF ADMINISTRATION' should be revised to:

Route of administration: nasal or pharyngeal.

Children 2 to 4 years. 1 squirt per nostril.

Children 4 to 8 years. 2 squirts per nostril.

Children 8 to 12 years. 3 squirts per nostril.

Adults, children over 12 years. Up to 5 squirts per nostril.

Each squirt measures 100 microlitres.

Method of administration

Prime pump five times before use.

Do not exceed the recommended dosage regimens.

Doses are to be administered once only.

For single use in one patient only.

Any unused product should be discarded.

- The information: *"Children under 2 years of age"* in Section 4.3: 'CONTRAINDICATIONS' should be cross-referenced to Section 4.4: 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use'.

- The information in Section 4.4: 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use' should be revised to: 'Do not administer to children under 2 years of age' and cross-referenced to Section 4.3: 'CONTRAINDICATIONS'.

- The information in Section 4.6: 'FERTILITY, PREGNANCY AND LACTATION - Use in pregnancy' should be revised to: 'Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Section 4.3: 'CONTRAINDICATIONS'). Australian Pregnancy Categorisation: Category B2 - Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

- The information in Section 4.7: 'EFFECTS ON ABILITY TO DRIVE AND USE MACHINES' should be revised to the standard text: 'The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration'.

- The information in Section 6.4: 'SPECIAL PRECAUTIONS FOR STORAGE' should be revised to: 'Store below 25°C. Protect from light'.

- The information in Section 6.5: 'NATURE AND CONTENTS OF CONTAINER' should be revised to: 'Glass bottle sealed with a rubber

stopper and a plastic wad-less screw cap. The spray pump and actuator consist of polypropylenes and polyethylenes. 2.5 mL and 50 mL pack sizes'.

9. As of 2 June 2020, you have confirmed that the PI document approved at initial registration has now been reformatted to the new format. This change should be captured by the change code: DRF [C1 – 9D(3)].

The related eBS application has been amended accordingly and 'sponsor verification' of your application is required.

Please check your application carefully.

To verify the application details, click on the "View submissions" link on the TGA Business Services homepage.

Click the 'down arrow' on the left hand side of the product listing, then click "Print Preview". This will show the original application and TGA revised application on the same screen.

After reviewing, click "Continue" (top left, under "I agree with the changes:"). This will open the Declaration page. Click "Agree"

Please let me know by return email once you have verified the application.

If any clarification is required please call me to discuss.

Please note if your registration application was submitted in eCTD (or NeeS) format (i.e. with an e-identifier / sequence number), please ensure that

- all responses to queries; and
- all subsequent change applications

continue to be in eCTD (or NeeS) format. In this case, responses to queries should also be copied to eSubmissions@health.gov.au .

Regards

s22
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

OTC Medicines Evaluation
Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

17 June 2020

Re: Response to OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of evaluation - request for information.

ELECTRONIC SUBMISSION DETAILS

Format	NeeS Australia
eSubmission identifier	n004445
Applicant	Bioinnova Pty Ltd: 68187
Products	AUST R 225750: LIDOPHENYL SPRAY bottle
Sequence type	OTC – C2
Regulatory activity lead	OTC
Sequence description	Supplementary information
Sequence number	0009
Related sequence	0008
Date	2020.06.17
Electronic media	Electronic via eBS portal
Submission size	~ 10 MB
Validation	Lorenz eValidator version 18.1

Dear Sir/Madam,

Please find herewith our response to the OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of evaluation - request for information.

I trust the information provided is satisfactory. However, should you wish to discuss this application please do not hesistate to contact me with the details below.

Yours sincerely,

s22 [redacted]
s22 [redacted]
Director-Regulatory Affairs
s22 [redacted]@bioinnova.com.au
Phone: s22 [redacted]

Tracking table

Sequence	Related substance	Sequence type	Submission Description	Date of Submission
0000	0000	OTC-C2 variation	Initial	February 2019
0001	0000	Supplementary information	Response to request for information	June 2019
0002	0002	OTC-C2 variation	Initial	September 2019
0003	0002	Supplementary information	Response to request for information	November 2019
0004	0003	Supplementary information	Response to request for information	January 2020
0005	0005	OTC-C2 variation and Notification	Initial	February 2020
0006	0006	Withdrawal of 0005 sequence	Withdrawal	March 2020
0007	0007	OTC-C2 variation	Initial	March 2020
0008	0008	Supplementary information	Response to request for information	April 2020
0009	0008	Supplementary information	Response to request for information	June 2020

Response to OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - outcome of evaluation - request for information.

1. As per TGO 92 s.8(2)(b), it would appear the proposed critical health information (CHI) on the primary pack (carton) label does not present the appropriate headings in the mandatory order due to:
   - the CHI being split over two panels which are not adjacent, and
   - there is no indication that the CHI continues from the first to the second panel [see 'Medicine labels - Guidance on TGO 91 and TGO 92' (Version 2.1, July 2019)].

To rectify this situation the following battery of revision is recommended:
- The carton labelling should be reformatted such that the two panels upon which the CHI is located are adjacent to each other from left (first panel) to right (second panel);
- Place the word 'continued…' at the right bottom corner of the first panel and use an arrow head (▻) at the end of 'continued…' to mark the direction of the continuation; and
- Title the subsequent panel 'MEDICINE INFORMATION (continued)'.

2. To improve comprehension and readability it is suggested that the information under the heading: 'WARNINGS' of the CHI on the primary pack (carton) label be reworked and reformatted as follows:

   WARNINGS:
   Not for use in children under 2 years of age or during pregnancy.
   Must be used with caution in patients who have cardiovascular disease.
   For professional use only.
   For external use only.
   For topical use only.
   Not for injection.

3. As per TGO 92 s.8(2), the bar code under the heading: 'WARNINGS' must be relocated outside of the CHI on the primary pack (carton) label.

4. To improve comprehension and readability it is suggested that the information under the heading: 'DIRECTIONS FOR USE' of the CHI on the primary pack (carton) label be reworked and reformatted as follows:
   DIRECTIONS FOR USE:
   Prime pump 5 times before use.
   Each squirt contains 100 microlitres.
   Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner.
   Read enclosed leaflet before use.
   Doses are to be administered once only.
   Dosage for nasal and pharyngeal administration:

5. As per TGO 92 s.8(2)(e), the information: *"Mfg. Lic. No.: AD/009"* under the heading: 'OTHER INFORMATION' must be relocated outside of the CHI on the primary pack (carton) label.

6. For consistency, these suggested changes to the primary pack (carton) label may also be applied appropriately to the container (bottle) label.

Response: We acknowledge TGA's comment's and accordingly updated label is enclosed in M1 Section 1.3

7. The sponsor should provide an assurance that the batch number of the medicine preceded by the batch number prefix and the expiry date of the medicine preceded by the expiry date prefix will be displayed on the primary pack (carton) labelling.

Response: We assure that the batch number of the medicine preceded by the batch number prefix and the expiry date of the medicine preceded by the expiry date prefix will be displayed on the primary pack (carton) labelling.

8. The sponsor should refer to the *Form for providing product information* on the TGA website (https://www.tga.gov.au/reformatting-product-information-frequently-asked-questions) and make the following revisions to the revised and reformatted PI:

- The title of the document should be revised to: 'AUSTRALIAN PRODUCT INFORMATION – LIDOPHENYL SPRAY (Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride)'.
- The information in Section 2: 'QUALITATIVE AND QUANTITATIVE COMPOSITION' should be revised to: 'Lidocaine (lignocaine) hydrochloride 5 mg/actuation (5% w/v) and Phenylephrine hydrochloride 0.5 mg/actuation (0.5% w/v). This product does not contain any antimicrobial agent. For the full list of excipients, see Section 6.1 List of excipients'.
- The information in Section 3: 'PHARMACEUTICAL FORM' should be revised to: 'Pump actuated topical nasal spray which is a clear, colourless, sterile solution and should not be used if it is coloured'.
- The information in Section 4.2: 'DOSE AND METHOD OF ADMINISTRATION' should be revised to:

Route of administration: nasal or pharyngeal.
Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril.
Each squirt measures 100 microlitres.
Method of administration
Prime pump five times before use.
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
For single use in one patient only.
Any unused product should be discarded.

- The information: *"Children under 2 years of age"* in Section 4.3: 'CONTRAINDICATIONS' should be cross-referenced to Section 4.4: 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use'.

- The information in Section 4.4: ‘SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use’ should be revised to: ‘Do not administer to children under 2 years of age’ and cross-referenced to Section 4.3: ‘CONTRAINDICATIONS’.
- The information in Section 4.6: ‘FERTILITY, PREGNANCY AND LACTATION - Use in pregnancy’ should be revised to: ‘Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Section 4.3: ‘CONTRAINDICATIONS’). Australian Pregnancy Categorisation: Category B2 - Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.
- The information in Section 4.7: ‘EFFECTS ON ABILITY TO DRIVE AND USE MACHINES’ should be revised to the standard text: ‘The effects of this medicine on a person’s ability to drive and use machines were not assessed as part of its registration’.
- The information in Section 6.4: ‘SPECIAL PRECAUTIONS FOR STORAGE’ should be revised to: ‘Store below 25°C. Protect from light’.
- The information in Section 6.5: ‘NATURE AND CONTENTS OF CONTAINER’ should be revised to: ‘Glass bottle sealed with a rubber stopper and a plastic wad-less screw cap. The spray pump and actuator consist of polypropylenes and polyethylenes. 2.5 mL and 50 mL pack sizes’.

Response: We acknowledge TGA’s comment’s and accordingly clean and annotated PI is enclosed in M1 Section 1.3

AUSTRALIAN PRODUCT INFORMATION – LIDOPHENYL SPRAY
(Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride)

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine (lignocaine) hydrochloride 5 mg/actuation (5% w/v) and Phenylephrine hydrochloride 0.5 mg/actuation (0.5% w/v). This product does not contain any antimicrobial agent.

For the full list of excipients, see Section 6.1 List of excipients'.

3 PHARMACEUTICAL FORM

Pump actuated topical nasal spray which is a clear, colourless, sterile solution and should not be used if it is coloured.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Route of administration: nasal or pharyngeal.
Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril.

Each squirt measures 100 microlitres.

Method of administration

Prime pump five times before use.
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
For single use in one patient only.
Any unused product should be discarded.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age. see Section 4.4: 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use'.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

Do not administer to children under 2 years of age. see Section 4.3: 'CONTRAINDICATIONS'.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Section 4.3: 'CONTRAINDICATIONS'). Australian Pregnancy Categorisation: Category B2 - Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

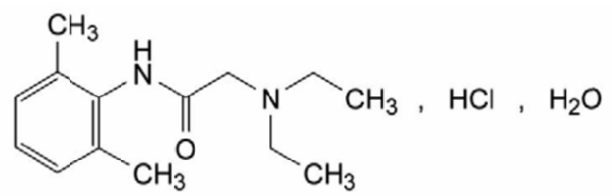
Glass bottle sealed with a rubber stopper and a plastic wad-less screw cap.
The spray pump and actuator and bottle consist of polypropylenes and polyethylenes. 2.5 mL and 50 mL pack sizes'.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

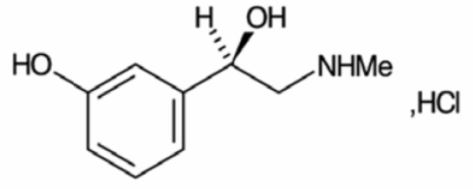
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 4.2	Removed text on nozzle.
Section 4.4	Paediatric use informatio0n added
Section 4.6	Use in pregnancy information added.
Section 4.7	standard text added as per requirement

AUSTRALIAN PRODUCT INFORMATION – LIDOPHENYL SPRAY
(Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride) ~~LidoPhenyl Spray~~

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine (lignocaine) hydrochloride 5 mg/actuation (5% w/v) and Phenylephrine hydrochloride 0.5 mg/actuation (0.5% w/v). This product does not contain any antimicrobial agent.

For the full list of excipients, see Section 6.1 List of excipients' ~~It contains Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v. This product does not contain any antimicrobial agent. It is a clear, colourless, sterile solution and should not be used if it is coloured.~~

~~For the full list of excipients, see Section 6.1 List of excipients.~~

3 PHARMACEUTICAL FORM

Pump actuated topical nasal spray which is a clear, colourless, sterile solution and should not be used if it is coloured. ~~Topical solution, Pump actuated~~

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Route of administration: nasal or pharyngeal.
Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril.

Each squirt measures 100 microlitres.
~~*Children 2 to 4 years.* 1 squirt per nostril.~~
~~*Children 4 to 8 years.* 2 squirts per nostril.~~

Formatted: Font: (Default) Times New Roman, 12 pt, Bold, Font color: Auto, Pattern: Clear
Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear
Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear
Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear
Formatted: Justified, Space Before: 6 pt, After: 6 pt
Formatted: Font: Not Expanded by / Condensed by
Formatted: Font: (Default) Times New Roman, Font color: Auto, Pattern: Clear
Formatted: Font: (Default) Times New Roman, Font color: Auto, English (United States)
Formatted: Body Text, Indent: Left: 0 cm, Don't swap indents on facing pages, Pattern: Clear
Formatted: Body Text, Don't swap indents on facing pages, Pattern: Clear
Formatted: Body Text, Indent: Left: 0 cm, Don't swap indents on facing pages, Pattern: Clear

~~*Children 8 to 12 years.* 3 squirts per nostril.~~
~~*Adults, children over 12 years.* Up to 5 squirts per nostril. Each squirt measures 100 microlitres.~~

Method of administration

Prime pump five times before use.
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
For single use in one patient only.
Any unused product should be discarded.
~~Route of administration: nasal or pharyngeal.~~
~~Do not exceed the recommended dosage regimens.~~
~~Do not administer to children under 2 years of age.~~
~~Doses are to be administered once only.~~

Formatted: Font: (Default) Times New Roman, Font color: Auto

Formatted: Body Text, Indent: Left: 0 cm, Pattern: Clear

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age. see Section 4.4: 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use'.

Formatted: Font: (Default) Times New Roman, Font color: Auto, Pattern: Clear

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

Do not administer to children under 2 years of age. see Section 4.3: 'CONTRAINDICATIONS' ~~No data available.~~

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium**- Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Section 4.3: 'CONTRAINDICATIONS'). Australian Pregnancy Categorisation: Category B2 - Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.~~**Australian Pregnancy** Categorisation: **Category B2-** Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Contraindications). Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.~~

Formatted: Font: (Default) Times New Roman, Font color: Auto, Condensed by 0.05 pt, Pattern: Clear

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.~~No data available.~~

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, English (Australia), Pattern: Clear

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine). The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light. ~~This product does not contain antimicrobial agents. For single use in one patient only. Any unused product should be discarded.~~

6.5 NATURE AND CONTENTS OF CONTAINER

Glass bottle sealed with a rubber stopper and a plastic wad-less screw cap.
The spray pump and actuator and bottle consist of polypropylenes and polyethylenes. 2.5 mL and 50 mL pack sizes'.~~Pump actuated topical solution:~~
~~Lidocaine (lignocaine) 5 mg, phenylephrine 0.5 mg)/spray~~
~~2.5 mL and 50 mL~~

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, English (Australia), Pattern: Clear

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, English (Australia), Pattern: Clear

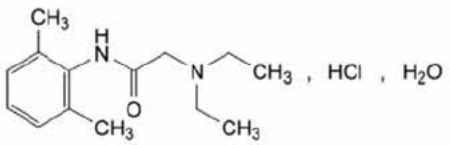
Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, English (Australia), Pattern: Clear

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

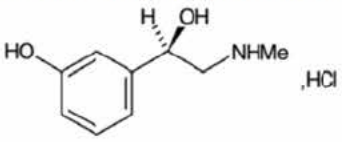
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 4.2	Removed text on nozzle.
Section 4.4	Paediatric use informatio0n added
Section 4.6	Use in pregnancy information added.
Section 4.7	standard text added as per requirement

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto, Pattern: Clear

Nasal Spray
Vasoconstrictor
Anaesthetic

LidoPhenyl™
Spray

Lidocaine (Lignocaine) hydrochloride
5 mg/actuation
and Phenylephrine hydrochloride
0.5 mg/actuation

NOZZLE SUPPLY

One LP Nozzle™ is available inside.

LP Nozzle™ available separately.

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:

ACTIVE INGREDIENT:

Lidocaine (Lignocaine) hydrochloride 5 mg/actuation
and Phenylephrine hydrochloride 0.5 mg/actuation

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:

Not for use in children under 2 years of age or during pregnancy.
Must be used with caution in patients who have cardiovascular disease.
For professional use only.
For external use only.
For topical use only.
Not for injection.

Continued →

MEDICINE INFORMATION (continued)

DIRECTIONS FOR USE:

Prime pump 5 times before use.
Each squirt contains 100 microlitres.
Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner.
Read enclosed leaflet before use.
Doses are to be administered once only.
Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4-8 years	2 squirts per nostril
2-4 years	1 squirt per nostril

OTHER INFORMATION

Store below 25°C. Protect from light.

Distributor:
BioInnova Pty Ltd
U-37, 14 Loyalty Road, North Rocks,
NSW 2151 Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

9 356393 000013

Mfg. Lic. No.: AD/009

LOT:

EXP:

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl™
Spray

Lidocaine (Lignocaine) hydrochloride
5 mg/actuation
and Phenylephrine hydrochloride
0.5 mg/actuation

Anaesthetic
Vasoconstrictor
Nasal Spray

480
Metered Doses

Peppermint Flavour

For Single use only.
50 mL

AUST R 225750

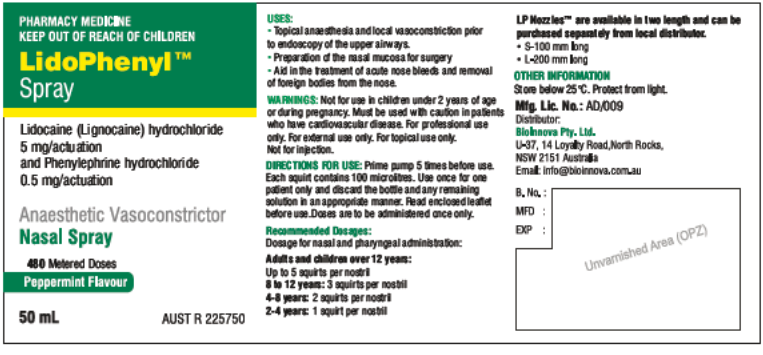
Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT



100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

From: s22
To: s22
Cc: OTC Medicines; COMB Systems
Subject: OM-2020-00259-1 - LIDOPHENYL SPRAY bottle (AUST R 225750) - approval letter [SEC=OFFICIAL]
Date: Thursday, 2 July 2020 10:51:21 AM
Attachments: OM-2020-00259-1; LIDOPHENYL SPRAY bottle (AUST R 225750); approval letter.PDF

Dear Sponsor,

Please find attached an electronic copy of the approval letter for your C2 level application OM-2020-00259-1.

This will be the only copy provided unless otherwise requested.

Before the goods can be included in the Register, you are required to either:
. notify the Secretary using the approved form that the patent certification under subsection 26B(1) is not required in relation to the application; OR
. provide a certificate required under subsection 26B(1) of the Act.
The requirement for patent certificates does not apply to applicants for registration of medicines who are not required to submit evidence or information to establish the safety or efficacy of the goods as part of the registration process. In these circumstances, the applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the application.
The notification form and patent certificate can be downloaded via the TGA website (http://www.tga.gov.au/about/international-usa-fta.htm). Please email a copy to OTC.Medicines@health.gov.au.

As noted above, a Certificate of Registration can only be issued after receipt of the completed and signed form or certificate.

Regards

s22
Professional Officer
OTC Medicines Evaluation
Complementary and OTC Medicines Branch

Phone: s22 Fax: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

Submission ID: OM-2020-00259-1
Our reference: D20-954864

The Managing Director
Bioinnova Pty Ltd
Unit 37
North Rocks NSW 2151

Attention: s22 [redacted] Regulatory Affairs

Dear Sir/Madam

APPLICATION UNDER s. 23 TO REGISTER A NEW MEDICINE UNDER s. 25 IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

I refer to your application under section 23 of the *Therapeutic Goods Act 1989* (the Act) dated 24 March 2020 to register

LIDOPHENYL SPRAY bottle

(the medicine) in the Australian Register of Therapeutic Goods (the ARTG) which, while a separate and distinct good under subsection 16(1) of the Act, is the same as registered medicine: LIDOPHENYL SPRAY bottle (AUST R 225750) (the "currently registered medicine") except as follows:

- Increase in the amount of existing flavour ingredients, as described in your letter dated 30 April 2020.

Decision

As delegate of the Secretary of the Department of Health, I am:

- under subsection 25(3) of the Act, approving the registration of the medicine in the ARTG on the basis that the only difference between the proposed medicine and the currently registered medicine is
  - An increase in the amount of existing flavour ingredients, and
  - Changes to the product labelling, Product Information document and Consumer Medicines Information as a package insert, as described in your letter dated 30 April 2020 and your correspondence of 18 June 2020.
- under subsection 25AB(2) of the Act, notifying you of the decision to register the medicine,
- under subsections 25AA(1) of the Act, approving the text of the PI for the medicine on the basis that the only changes made to the most recently approved PI for the currently-registered product were those set out in your request of 18 June 2020,
- under paragraph 25AB(3)(b) of the Act, notifying you of the approved PI as set out at **Attachment 2**, and

- under subsection 28(2B) of the Act, applying conditions of registration of the medicine, as outlined under '**Conditions of Registration**' below.

Section 25, subsections 25AA(1) and (1A), section 25AB and section 28 of the Act can be found online at the following link: https://www.legislation.gov.au/Series/C2004A03952

Date of effect and supply

Under subsection 16(1) of the Act, the new medicine is a separate and distinct good. However, because you have indicated that the new medicine will replace the existing medicine, the same AUST R number may be used by reason of the Therapeutic Goods (Groups) Order No. 1 of 2001.

The date of effect of the new registration is the date specified in the Certificate of Registration, a copy of which may be obtained via the eBusiness Services (eBS) facilities shortly after receipt of the patent certification requested below. This should be the date included under the heading "date of the most recent amendment" at the end of the approved PI as set out at **Attachment 2**.

Conditions of registration

The conditions applying to the new registration of the medicine are:

1. Conditions applicable to all therapeutic goods as specified in the current edition of the document "Conditions- standard and specific: Applying to registered or listed therapeutic goods under section 28 of the *Therapeutic Goods Act 1989*", and
2. Conditions applicable to the relevant category and class of therapeutic goods as specified in the current edition of the document " Conditions- standard and specific: Applying to registered or listed therapeutic goods under section 28 of the *Therapeutic Goods Act 1989*", and
3. The following specific conditions:

    a. Stability testing program must be initiated on the first two production batches of the goods, in accordance with the requirements of the TGA's guidelines on the stability testing of pharmaceuticals, as outlined in the TGA document Australian Regulatory Guidelines for OTC Medicines (ARGOM), and any adverse results must be immediately reported to the TGA.

    b. The manufacturing process will be validated according to the requirements of the Code of Good Manufacturing Practice [the Therapeutic Goods (Manufacturing Principles) Determination No. 1 2013 contains a definition of 'the Code'], and that the manufacturer's validation report and related information will be available for review, on request, by the TGA within 3 months of release for supply of the first production batch.

Action required of you

Before the medicine can be included in the ARTG, you are required to either:

- notify the Secretary using the approved form that the patent certification under subsection 26B(1) of the Act is not required in relation to the application; or
- provide a certificate required under subsection 26B(1) of the Act.

Note:
The requirement for patent certificates does not apply to applicants for registration of medicines who are not required to submit evidence or information to establish the safety or efficacy of the

goods as part of the registration process. In these circumstances, the applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the application.

The notification form and patent certificate can be downloaded via the TGA website (http://www.tga.gov.au/form/australia-united-states-free-trade-agreement). You should forward the completed and signed certificate or notification to otc.medicines@health.gov.au. A certificate of registration can only be issued after receipt of the completed and signed certificate or notification.

Review rights

Details of your review rights are at **Attachment 1**.

Your obligations in relation to Product Information

You are reminded that an approved PI for a medicine cannot be changed without the approval of the Secretary under subsection 25AA(4) of the Act.

You are also reminded that the CMI must comply with the requirements set out in the Therapeutic Goods Regulations 1990 which includes the obligation to ensure the CMI that must be supplied with the medicine is 'consistent with' the approved PI.

Other matters

Copies of the final medicine labels are provided at **Attachment 3**. Please note that your product labels have not been evaluated for compliance with State and Territory labelling requirements.

A copy of the final consumer medicine information as a package insert is provided at **Attachment 4**.

You are reminded of the pharmacovigilance reporting requirements as set out in the document "*Pharmacovigilance responsibilities of medicine sponsors – Australian recommendations and requirements*", including the requirement to keep the Australian pharmacovigilance contact person details up to date through the TGA Business Services electronic portal.

Please note that it is your responsibility to ensure that current Good Manufacturing Practice clearance letters are maintained for all overseas sites of manufacture registered for the products.

Please do not hesitate to contact me if you have any further queries regarding this matter.

Yours faithfully

Signed and authorised by
s22 [redacted]
Delegate of the Secretary
Complementary & OTC Medicines Branch
Email: s22 [redacted] @health.gov.au

2 July 2020

Attachments:

1. Review rights
2. A copy of approved product information
3. A copy of final medicine labels
4. A copy of final consumer medicine information as a package insert

Attachment 1

Request for reconsideration of an initial decision

The decisions under sections 25 and 28 of the Act are 'initial decisions' within the meaning of section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted. The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and '**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

AUSTRALIAN PRODUCT INFORMATION – LIDOPHENYL SPRAY
(Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride)

1 NAME OF THE MEDICINE

Lidocaine (lignocaine) hydrochloride and Phenylephrine hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine (lignocaine) hydrochloride 5 mg/actuation (5% w/v) and Phenylephrine hydrochloride 0.5 mg/actuation (0.5% w/v). This product does not contain any antimicrobial agent.

For the full list of excipients, see Section 6.1 List of excipients'.

3 PHARMACEUTICAL FORM

Pump actuated topical nasal spray which is a clear, colourless, sterile solution and should not be used if it is coloured.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Preparation of nasal mucosa for surgery or endoscopy.
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.
- Topical anaesthesia prior to indirect or direct laryngoscopy
- Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

4.2 DOSE AND METHOD OF ADMINISTRATION

Route of administration: nasal or pharyngeal.
Children 2 to 4 years. 1 squirt per nostril.
Children 4 to 8 years. 2 squirts per nostril.
Children 8 to 12 years. 3 squirts per nostril.
Adults, children over 12 years. Up to 5 squirts per nostril.

Each squirt measures 100 microlitres.

Method of administration

Prime pump five times before use.
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
For single use in one patient only.
Any unused product should be discarded.

4.3 CONTRAINDICATIONS

- Known hypersensitivity to either of the active ingredients or any of the non-active ingredients as listed under 6.1 Ingredients.
- Hypersensitivity to other local anaesthetics of the amide type and to other sympathomimetic agents.
- Pregnancy.
- Children under 2 years of age. see Section 4.4: 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE - Paediatric use'.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General precautions
Genetic predisposition to malignant hyperthermia and pre-existing abnormal neurological conditions.

Eating and drinking
The use of topical anaesthetic agents in the oral cavity and upper airway tissues may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within two hours of using local anaesthetics in the mouth area. Numbness of the tongue or buccal mucosa may increase the risk of trauma from hot drinks or biting.

Patients with cardiovascular diseases
Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should be given with caution to patients with cardiovascular disease, especially those suffering from hypertension, severe bradycardia, conduction disturbances or severe digitalis intoxication.

There is a small but transient increase in pulse (up to 12 beats per minute) and blood pressure (average 8.2 mmHg systolic and 7.5 mmHg diastolic) lasting for ten minutes after the administration of this medication to healthy individuals. This must be taken into account if this medication is given to hypertensive patients.

Paediatric use

Do not administer to children under 2 years of age. see Section 4.3: 'CONTRAINDICATIONS'.

Use in hepatic impairment

Lidocaine (lignocaine) is metabolised in the liver and must be given with caution to patients with hepatic insufficiency.

Use in renal impairment

Metabolites of Lidocaine (lignocaine) may accumulate in patients with renal impairment.

Use in the elderly

Elderly and debilitated patients should be given reduced dosages.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Propanolol or cimetidine may reduce the clearance of Lidocaine (lignocaine) so that patients given these drugs together may show signs of Lidocaine (lignocaine) toxicity. They should be closely observed.

Antiarrhythmic drugs - Lidocaine (lignocaine) can have additive effects or antagonistic effects. **Suxamethonium-** Lidocaine (lignocaine) prolongs the action of suxamethonium.

Phenytoin- Lidocaine (lignocaine) and phenytoin have additive cardiac depressant effects.

Antidepressants- May interact with phenylephrine.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v should not be used in pregnancy (see Section 4.3: 'CONTRAINDICATIONS'). Australian Pregnancy Categorisation: Category B2 - Lidocaine (lignocaine) is classified in category A, but Phenylephrine is in category B2.

Use in lactation

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v may be used as directed in breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Phenylepherine may rarely cause tremor or palpitations. Rarely nervousness, nausea, vomiting, tinnitus, dizziness, numbness or disorientation may occur following rapid absorption of Lidocaine (lignocaine**)**. The most commonly noted side effect is a transient bitter taste in the mouth lasting one to two minutes and then disappearing

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms:
Systemic toxicity is manifested by central nervous system excitation such as restlessness, excitement, blurred vision, nausea and vomiting, muscle twitching and, in more severe cases, convulsions. Toxicity due to α-adrenergic overstimulation may result in tachycardia and arrhythmia.

Treatment:
Consists of ensuring adequate ventilation and arresting convulsions with intravenous diazepam if required. Cardiac resuscitation may be required to reverse pathological arrhythmias.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lidocaine (lignocaine) hydrochloride. This constituent is a local anaesthetic which stabilises the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. Onset of action is rapid and may last for one hour. It does not produce irritation to mucous membranes due to its nonester structure and it is not detoxified by circulating plasma esterases. The liver is the chief site of biotransformation of Lidocaine (lignocaine) and both free and conjugated forms of the drug are excreted in the urine.

Phenylephrine hydrochloride. This is a sympathomimetic agent with mainly direct effects on the α-adrenoreceptors. The phenylepherine in Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v constricts the blood vessels locally, which can decrease the systemic absorption of Lidocaine (lignocaine) and restrict bleeding. It also decreases the onset of action and increases the duration of action of Lidocaine (lignocaine). Its nasal decongestant action can assist in easier passage of endoscopes.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections BP
Dilute hydrochloric acid
Sodium hydroxide
Stevia rebaudiana
Concentrated Peppermint Water
Acesulfame Potassium
Sodium Chloride

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

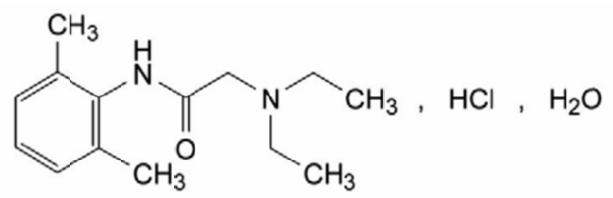
Glass bottle sealed with a rubber stopper and a plastic wad-less screw cap.
The spray pump and actuator and bottle consist of polypropylenes and polyethylenes. 2.5 mL and 50 mL pack sizes'.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

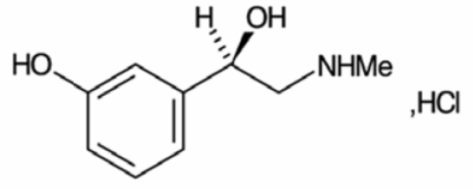
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy (or) any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

The chemical structure for Lidocaine(lignocaine) hydrochloride is:



The chemical structure for phenylephrine hydrochloride is:



CAS Number: Lidocaine (lignocaine) hydrochloride: 6108-050-0 and phenylephrine hydrochloride: 61-76-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2

8 SPONSOR

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

9 DATE OF FIRST APPROVAL

14 July 2014

10 DATE OF REVISION

XX-MM-YYYY

Summary table of changes

Section changed	Summary of new information
All sections	Changed as per New PI format
8 SPONSOR	Sponsor name and address changed.
6.1 Ingredient	New proposed ingredient included
Heading of PI	Change in Trade name
8 SPONSOR	Sponsor name and address changed
All Sections	Changed naming of active substance Lidocaine (Lignocaine) Dual naming as per requirement
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 6.4	Changed storage information for 2.5mL and 50 mL pack size
Section 4.2	Removed text on nozzle.
Section 4.4	Paediatric use informatio0n added
Section 4.6	Use in pregnancy information added.
Section 4.7	standard text added as per requirement

Anaesthetic
Vasoconstrictor
Nasal Spray

LidoPhenyl™
Spray

Lidocaine (Lignocaine) hydrochloride
5 mg/actuation
and Phenylephrine hydrochloride
0.5 mg/actuation

NOZZLE SUPPLY

One LP Nozzle™ is available inside.

LP Nozzle™ available separately.

LP Nozzles™ are available in two length and can be purchased separately from local distributor.

- S-100 mm long
- L-200 mm long

MEDICINE INFORMATION:

ACTIVE INGREDIENT:

Lidocaine (Lignocaine) hydrochloride 5 mg/actuation
and Phenylephrine hydrochloride 0.5 mg/actuation

USES:

- Topical anaesthesia and local vasoconstriction prior to endoscopy of the upper air ways
- Preparation of the nasal mucosa for surgery
- Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose.

WARNINGS:

Not for use in children under 2 years of age or during pregnancy.
Must be used with caution in patients who have cardiovascular disease.
For professional use only.
For external use only.
For topical use only.
Not for injection.

Continued →

MEDICINE INFORMATION (continued)

DIRECTIONS FOR USE:

Prime pump 5 times before use.
Each squirt contains 100 microlitres.
Use once for one patient only and discard the bottle and any remaining solution in an appropriate manner.
Read enclosed leaflet before use.
Doses are to be administered once only.
Dosage for nasal and pharyngeal administration:

Adults and children over 12 years	Up to 5 squirts per nostril
8 to 12 years	3 squirts per nostril
4 8 years	2 squirts per nostril
2 4 years	1 squirt per nostril

OTHER INFORMATION

Store below 25°C. Protect from light.

Distributor:
BioInnova Pty Ltd
U 37, 14 Loyalty Road, North Rocks,
NSW 2151 Australia
Email: info@bioinnova.com.au

DO NOT USE IF SEALS OVER CARTON ENDS ARE MISSING OR BROKEN

9 356393 000013

Mfg Lic No AD/009

LOT:

EXP:

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

LidoPhenyl™ Spray

Lidocaine (Lignocaine) hydrochloride
5 mg/actuation
and Phenylephrine hydrochloride
0.5 mg/actuation

Anaesthetic
Vasoconstrictor
Nasal Spray

480
Metered Doses

Peppermint Flavour

For Single use only.
50 mL

AUST R 225750

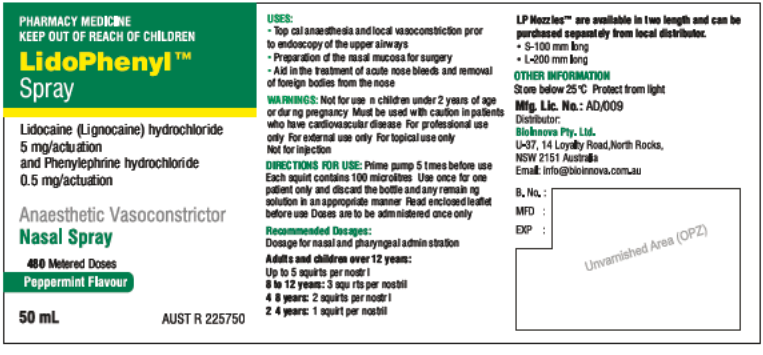
Size: 117 mm x 42 mm x 40 mm

s47

Size: 117 mm x 42 mm x 40 mm

PANTONE 347 C
PANTONE 165 C
PANTONE 294 C 15%
Black

Font: Swiss 721 CN BT



100 MM X 45 MM

s47

Size: 100 mm x 45 mm

PANTONE 347 C
PANTONE 165 C
Black

Font: Swiss 721 CN BT

LidoPhenyl spray aerosol (Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v)

PATIENT INFORMATION SHEET

What is in this medication and what it is used for

This solution contains two active ingredients Lidocaine (lignocaine) hydrochloride 5% w/v (50 mg/mL) and phenylephrine hydrochloride 0.5% w/v (5 mg/mL). Lidocaine (lignocaine)hydrochloride is a local anaesthetic and phenylephrine hydrochloride causes the small blood vessels near the surface of the tissue to constrict.

Lidocaine (lignocaine) hydrochloride 5% w/v and Phenylephrine hydrochloride 0.5% w/v contains no antimicrobial agent. This medicine should be used only once in one patient only and any residue discarded.
The solution also contains the following inactive ingredients: sodium hydroxide or dilute hydrochloric acid (to adjust pH) and Water for Injections, Stevia rebaudiana, Concentrated Peppermint Water, Acesulfame Potassium and Sodium Chloride.

Lidocaine (lignocaine)Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is most commonly used to numb the inside of your nose or throat before the surgeon operates or passes a fine telescope to view the structures of the nose and throat.

It may also be used to numb the nose if a foreign body (such as a small seed or bead or any other small object that becomes wedged in the nose) needs to be removed.

It may also be used to stop the bleeding from the front portion of the nose before treatment is given to seal the bleeding blood vessels.

What are the possible side effects?

The most common side effect that is noticed after use of this medicine is a bitter taste in the mouth, it only lasts for one to two minutes and then disappears. While other side effects are not commonly experienced with this medication because it is only administered as a single dose, it is possible for the following to occur:

A headache which might last for up to 20-30 minutes; drowsiness; light headedness; ringing in the ears; dizziness; confusion; blurred vision; vomiting; twitching; tremors; convulsions; sensations of hot or cold; slow heartbeat; fast heart rate with or without palpitations.

When you should not use this medicine.

- If you are pregnant, or may become pregnant.

When should you advise your doctor that you have other health problems or are taking other medication?

- If you are breast-feeding
- You have been given or used local anaesthetics before and had an allergic reaction, or have reacted to any of the ingredients listed above.
- You suffer from liver disease
- You have or have ever had heart disease (i.e. you have had a heart attack or have problems such as bradycardia which means a slower than normal heart beat rate. Lidocaine (lignocaine) the anaesthetic agent may make the effect of any heart rhythm regulating drugs much greater and therefore may adversely affect your heart)

- You suffer from kidney problems (kidney disease may change the concentrations of certain chemicals such as potassium in your blood, and this may in turn affect the action of Lidocaine (lignocaine) on the heart muscle)
- You suffer from epilepsy and are taking phenytoin (a medicine used to treat epilepsy) as use of phenytoin with this medicine may adversely affect your heart.
- You suffer from high blood pressure or an overactive thyroid.
- You are taking antidepressant medication.
- You are taking high blood pressure medication.
- You are taking anti-ulcer drugs such as Cimetidine. Cimetidine is known as an enzyme inducing drug. These drugs can cause the blood level of Lidocaine (lignocaine) (local anaesthetic agent) to rise to levels which can cause side effects.
- You have had an adverse reaction to phenylephrine or other decongestants (blood vessel squeezing drugs).

You should let your doctor or healthcare professional know if you are taking any other medicines, including ones you may have brought yourself without a prescription.

Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution should be used with caution on areas of the nose or throat which are cut because of the risk of increased absorption of the active ingredients leading to higher drug levels in the blood. Please let your doctor know if you have any cuts or sores in your nose.

What dose is to be used and how often is it given?

This medicine is administered into the nose or throat by your doctor or doctor's assistant in the following doses:

Adults and children over 12 years of ages:
Up to 5 squirts per nostril

8-12 years:
3 squirts per nostril

4-8 years:
2 squirts per nostril

2-4 years:
1 squirt per nostril

Each squirt measures 100 microlitres of fluid. The dose of Lidocaine (lignocaine) in each squirt is 5 mg, and the dose of phenylephrine in each squirt is 0.5 mg.

This medicine should not be used in children under 2 years of age.

These doses are given only once. The recommended dosage should not be exceeded.

What effects will I notice after taking the medication?

You will notice a feeling of numbness in the mouth, nose or throat which is caused by the medicine. You might also notice that the side of the nose to which the medication has been

applied becomes congested and may prove difficult to breathe through. This sensation will pass within a few hours.

What care needs to be taken after taking this medicine?

Do not drink or eat anything until the numbness in the throat has worn off. If you do, then it is possible that you may inhale food or drink into the lungs. This will result in serious illness.

Take care not to bite or to burn your tongue or cheek with hot liquids whilst the numbness is still present.

Storing this medicine

This medicine must be stored in a cool dry place under 25°C. Protect from light.

It should be out of sight and reach of children. Keep it in the same pack in which it was supplied.

Do not transfer it into another container.

Do not use it after the expiry date shown on the label and carton. If this medicine is out of date please return it to your pharmacist for correct disposal.

Further information

This leaflet provides only a summary of the information known about Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution. If you have any questions or want to know more about this medicine, or are unsure about anything, please ask your doctor or your pharmacist.

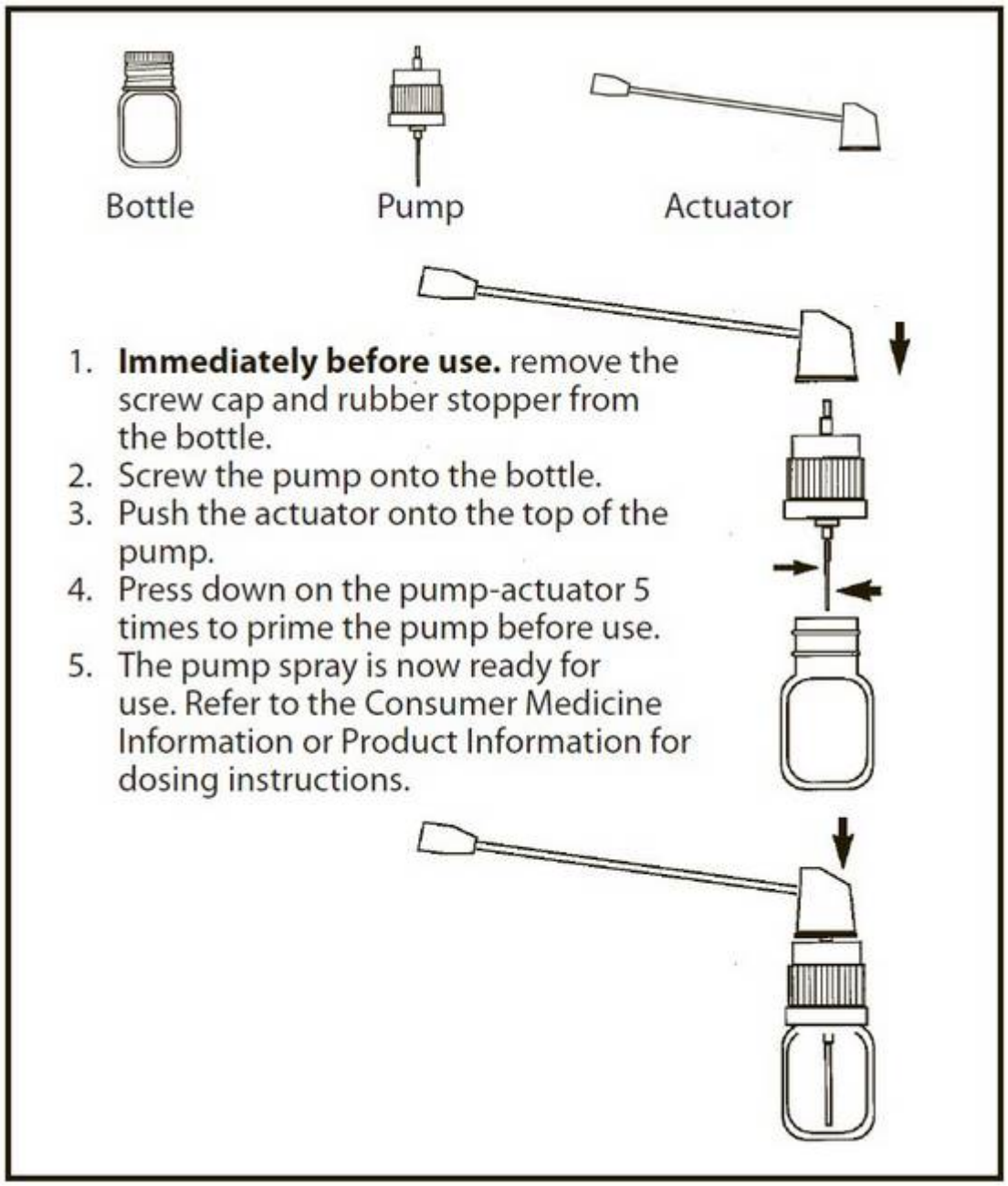
Lidocaine (lignocaine) Hydrochloride 5% w/v Phenylephrine Hydrochloride 0.5% w/v Topical Solution is supplied in Australia by:

BioInnova Pty Ltd
U-37, 14 Loyalty Road,
North Rocks NSW 2151
info@bioinnova.com.au

This leaflet was prepared April 2020.

Information for the Health Professional

User Guide - Instructions for Assembly of Pump and Actuator to Bottle



Priming the Pump.
While holding the bottle upright, the pump should be activated five times before use to prime it.

Dosage
Do not exceed the recommended dosage regimens.
Doses are to be administered once only.
Use with caution in patients with cardiovascular disease.

Other Information
Always hold the bottle upright to ensure dip-tube is immersed in the solution at its tip. The product is sterile until opened, and contains no preservatives. Use once in one patient only and discard the bottle and any remaining solution in an appropriate

manner.