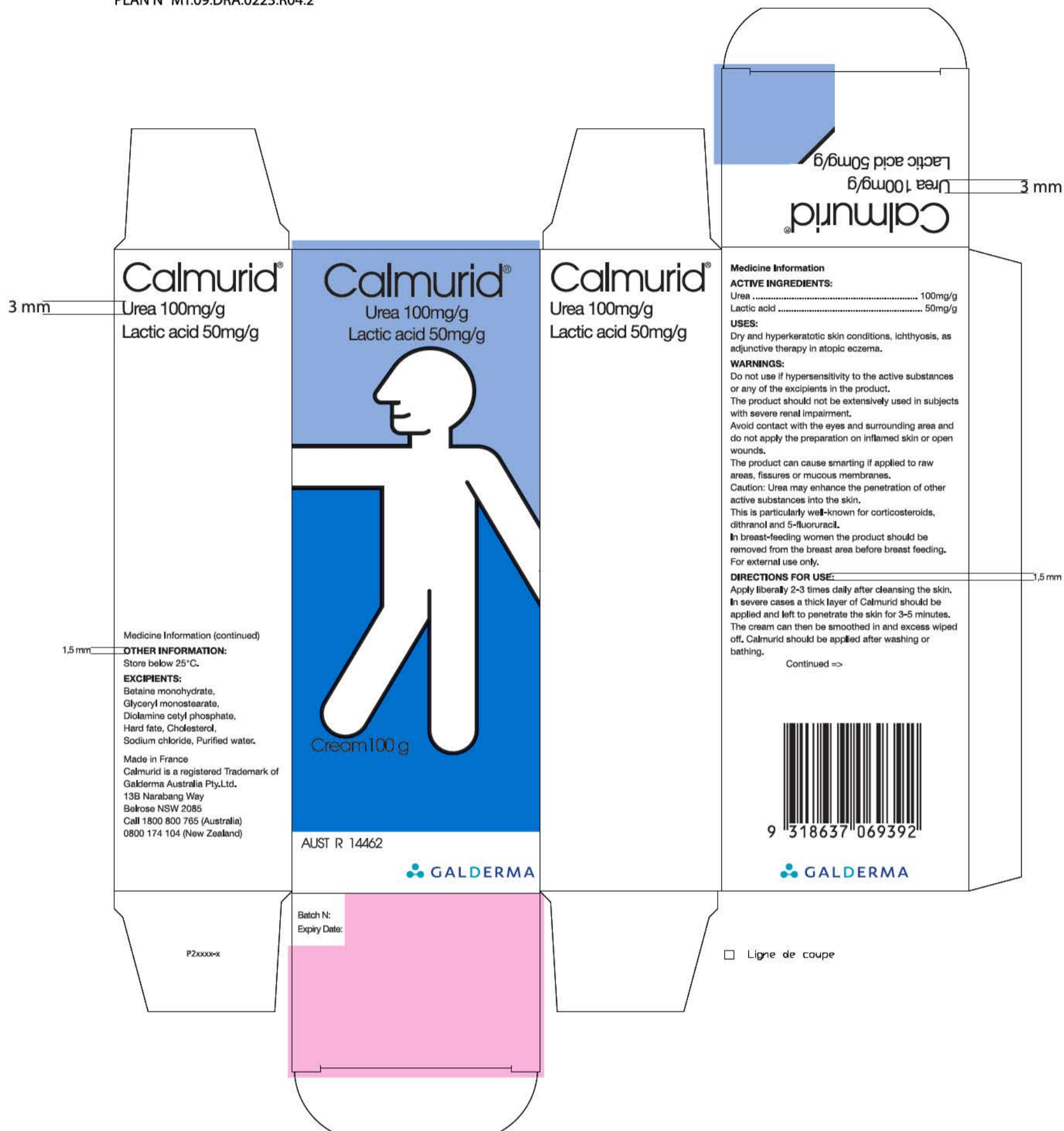
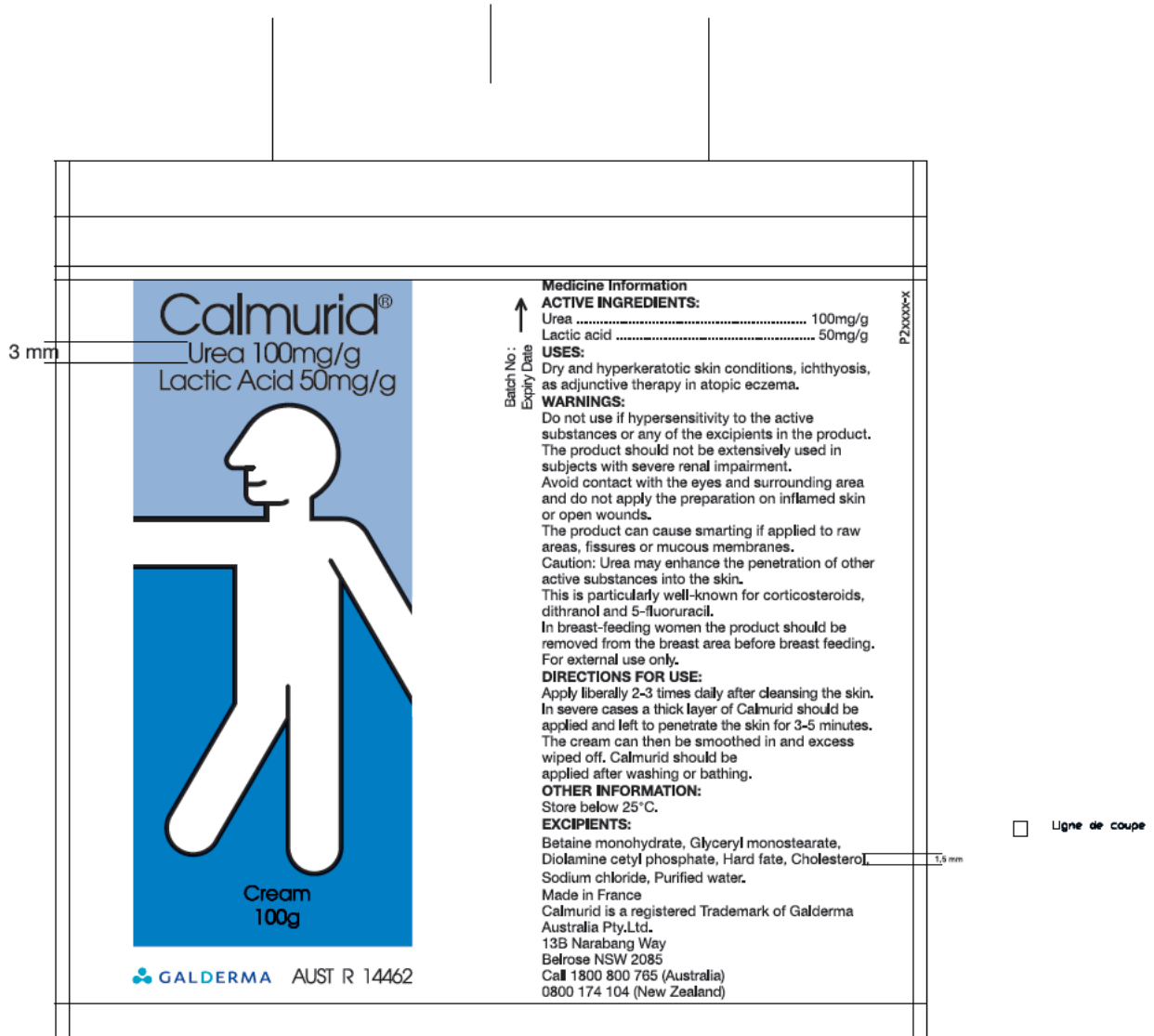







ETUI VERTICAL 56,5x41,5x147
 PLAN N° MT.09.DRA.0223.R04.2



Galderma Laboratories Product code: MOCK UP Product description: CALMURID CRE 100 Market: AUS Article: Carton Dimensions: 56,5x41,5x147 Pharmacode:TBD GRAPHIC DESIGNER: Xavier COLLOT LAUNCHING DEPARTMENT - Z.I. Galderma - 74540 ALBY-SUR-CHERAN - FRANCE	Printing Colors PMS BLUE 072C PMS 3135C PMS 285C BLACK	Artwork Approval Artwork approved by: Date: Signature:
	VARNISH FREE AREA DIELINES	This approval applies to whole text, including barcodes, pre-printed mentions and legal or special labelling constraints. PLEASE CHECK PROOF CAREFULLY TO ENSURE ALL ELEMENTS ARE CORRECT.

TUBE PLASTIQUE Ø40x125
 PLAN n° 2.GD.02.DRA.0012.R00



Galderma Laboratories	Printing Colors	Artwork Approval
Product code: MOCK UP	 PMS BLUE 072C	Artwork approved by: Date: Signature:
Product description: CALMURID CRE 100	 PMS 3135C	
Market: AUS	 PMS 285C	
Article: Plastic Tube	 BLACK	
Dimensions: 40x125		
Pharmacode: TBD		
GRAPHIC DESIGNER: Xavier COLLOT		
LAUNCHING DEPARTMENT - Z.I. Galderma - 74540 ALBY-SUR-CHERAN - FRANCE	 DIELINES	

TGA eBS Registration **Cancelled**

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
 Entry cancel date: 29/06/2020
 Reason: Cancelled by Sponsor
 Code Stock: No
 Evaluation area: Non-Prescription Medicines

- ▶ Sponsor
- ▶ Agent
- ▶ ExportNames
- ▶ Source history
- ▶ Variations
- ▶ Device information
- ▶ Conditions
- ▶ Comments
- ▶ Admin activity
- ▶ Financials
- ▶ Products
- ▶ Manufacturers
- ▶ Standards

Sponsor Information

Sponsor: Galderma Australia Pty Ltd
 Postal address: S22
 Australia
 Effective date: 01/06/1984

Sponsor history

Sponsor Id	Start Date	Sponsor name
17804	01/06/84	Galderma Australia Pty Ltd

TGA eBS Registration **Cancelled**

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
 Entry cancel date: 29/06/2020
 Reason: Cancelled by Sponsor
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- ▶ Sponsor
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- ▶ ExportNames
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- ▶ Products
- ▶ Manufacturers
- ▶ Standards

Source History Information

Source of entry: ARTG
 Source start date: 05/09/1991
 Source Id number: 14462

TGA eBS Registration **Cancelled**

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
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- ▶ Manufacturers
- ▶ Standards

Variations Information

Date	Code	Description	Comment
08/02/2018	LNT	Changes to bring a label into full compliance with TGO No. 92 - other than changes to the proprietary name. If changing proprietary name (and where grouping applies), also use code GPN or GPU	
08/02/2018	LSP	Changes to sponsor details including name and/or logo.	
08/02/2018	LSR	Addition of more restrictive safety-related statements	
08/02/2018	IHN	Update of ingredient name/s on labelling/product information in accordance with IHN project	
17/11/2014	MUP	Update a pre-clearance number	
18/09/2012	QSU	Deletion of an existing test	The sponsor is seeking to delete the viscosity test on the bulk product, since it believes that this in-process test is not significant
18/09/2012	QFE	Specification ranges - less restrictive	The sponsor is seeking to change the specifications of viscosity at release from 50,000-120,000mPa.s to 26,000-96,000mPa.s.
15/10/2010	QFE	Specification ranges - less restrictive	
15/10/2010	PSR	Shell life - decrease	

TGA eBS Registration Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
 Entry cancel date: 29/06/2020
 Reason: Cancelled by Sponsor
 Evaluation area: Non-Prescription Medicines Code Stock: No

- ▼ Sponsor
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- ▼ Standards

Standard Condition Information	
Code	Condition
28	Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
16	Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992.
15	Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992.
1	Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"
29	Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

TGA eBS Registration Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
 Entry cancel date: 29/06/2020
 Reason: Cancelled by Sponsor
 Evaluation area: Non-Prescription Medicines Code Stock: No

- ▼ Sponsor
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Comments Information		
Date	Standard comment	Text
08/02/2018	Variation to good	Changes to the product labelling, including: - Changes for compliance with TGO 32 requirements, - Addition of more restrictive, safety-related statements, - Ingredient name update, and - Update to the sponsor logo. Submission ID: OM-2017-01044-1 TRIM D 18-10105837
18/08/2012	Variation to good	Creating testing for viscosity of the bulk cream as an in-process control of manufacture, and changing the limits for viscosity of the cream in the batch release specification for the finished product. Submission ID: OM-2012-01104-3 File 2012/018233
15/10/2010	Variation to good	Changes to the finished product specifications - deletion of 'smooth' from the appearance specifications and widening of limit for ammonia content from 0.2% to 0.3%, decrease of shelf life from 3 years to 2 years. Submission ID: OM-2010-00013-3 File 95/7917
09/10/2007	Variation to good	CHANGE OF SPONSOR ADDRESS AND CONTACT DETAILS ON LABEL SUB ID OM-2007-3065-11, 1995/07917.
04/01/2007	Comments on updating a record	Changes as notified by Sponsor in update Submission ID OM-2006-3735-11 submitted on 13 December 2006.
03/07/2002	Comments unrelated to other codes - see fee text.	MANUF 8178 CHANGED TO 11345 FOLLOWING MERGER OF PHARMACA & UPJOHN SITE UNCHANGED
03/07/2002	Date of Supply Required	First supply from new manufacturer received on 14/9/95.
03/07/2002	NRTG Data - Not Checked	
03/07/2002	Variation to good	Change to manufacturer as described in the letter of 30 March 1995 from 990/07917.
03/07/2002	Grandfathered Product	

TGA eBS Registration Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
 Entry cancel date: 29/06/2020
 Reason: Cancelled by Sponsor
 Evaluation area: Non-Prescription Medicines Code Stock: No

- ▼ Sponsor
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- ▼ ExportNames
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Financial Information	
Charge level:	Registered Drug Prod (other than S4 and S8) Annual Charge
Exemption status:	
Billing function:	B\$1
Billing address:	\$22 Australia
Charge effective date:	
Invoice status:	

TGA eBS Product Cancelled

ARTG Entry: 14462 CALMURID cream tube
 A listed Manufacturer's Certificate has expired, or is expiring shortly.
 Sponsor: 17804 Galderma Australia Pty Ltd
 Product: 607422 CALMURID cream tube
 Licence therapeutic type: Medicine Registered
 Product type: Single Medicine Product
 Supplied:

- ▷ Supply and Status
- ▷ Device info.
- ▶ Medicine info.
- ▷ Shelf Life
- ▷ Sterility
- ▷ Conditions
- ▷ Indications
- ▷ Intended Use
- ▷ Warnings and Indication Requirements
- ▷ Comments
- ▷ Exceptions
- ▷ References
- ▷ Components

Medicine Information	
Product ATC info.	
Code	Description
D02AE	Carbamide products
Product info:	
Poison info.	
Pack size	Poison schedule
100g	Not scheduled. Not considered by committee
Chemical class:	
Generic parent ref:	
Practitioner only:	
Contains GMO:	
Contains Nanotechnology particles:	

TGA eBS Product Cancelled

ARTG Entry: 14462 CALMURID cream tube
 A listed Manufacturer's Certificate has expired, or is expiring shortly.
 Sponsor: 17804 Galderma Australia Pty Ltd
 Product: 607422 CALMURID cream tube
 Licence therapeutic type: Medicine Registered
 Product type: Single Medicine Product
 Supplied:

- ▷ Supply and Status
- ▷ Device info.
- ▷ Medicine info.
- ▶ Shelf Life
- ▷ Sterility
- ▷ Conditions
- ▷ Indications
- ▷ Intended Use
- ▷ Warnings and Indication Requirements
- ▷ Comments
- ▷ Exceptions
- ▷ References
- ▷ Components

Shelf Life Information						
Product Container						
Description	Material	Closure	Condition	Life Time	Temp	Shelf Life Conditions
Tube	Plastic		Closed	2 Years	Store below 25 degrees Celsius	
Shelf life info:						

TGA eBS Product Cancelled

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- ▷ Warnings and Indication Requirements
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- ▷ References
- ▷ Components

Product Specific Conditions	
Specific Conditions	
Changes as approved in the letter of 7 February 2018 from S22 submission ID: GM-2017-01044-1.	

TGA eBS Product Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 A listed Manufacturer's Certificate has expired, or is expiring shortly.
 Product: 607422 Galderma Australia Pty Ltd
 Licence therapeutic type: Medicine Registered CALMURID cream tube
 Product type: Single Medicine Product
 Supplied:

- ▷ Supply and Status
- ▷ Device info.
- ▷ Medicine info.
- ▷ Shelf Life
- ▷ Sterility
- ▷ Conditions
- ▷ Indications
- ▷ Intended Use
- ▷ Warnings and Indication Requirements
- ▷ Comments
- ▷ Exceptions
- ▷ References
- ▷ Components

Product Indications	
Specific indications	
Dry and hyperkeratotic skin conditions, ichthyosis, as adjunct therapy in atopic eczema.	

TGA eBS Product Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 A listed Manufacturer's Certificate has expired, or is expiring shortly.
 Product: 607422 Galderma Australia Pty Ltd
 Licence therapeutic type: Medicine Registered CALMURID cream tube
 Product type: Single Medicine Product
 Supplied:

- ▷ Supply and Status
- ▷ Device info.
- ▷ Medicine info.
- ▷ Shelf Life
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- ▷ Intended Use
- ▷ Warnings and Indication Requirements
- ▷ Comments
- ▷ Exceptions
- ▷ References
- ▷ Components

In House Product Reference Information		
Product lodgement info.		
Number	Lodgement date	Seq. Number
OM-2017-GL-12150-1	08/02/2018	

TGA eBS Product Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 A listed Manufacturer's Certificate has expired, or is expiring shortly.
 Product: 607422 Galderma Australia Pty Ltd
 Licence therapeutic type: Medicine Registered CALMURID cream tube
 Product type: Single Medicine Product
 Supplied:

- ▷ Supply and Status
- ▷ Device info.
- ▷ Medicine info.
- ▷ Shelf Life
- ▷ Sterility
- ▷ Conditions
- ▷ Indications
- ▷ Intended Use
- ▷ Warnings and Indication Requirements
- ▷ Comments
- ▷ Exceptions
- ▷ References
- ▷ Components

Components	
Id.	Description
514923	

TGA eBS Component

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Product: 807422 CALMURID cream tube
 Component: 514923
 Therapeutic type: Medicine Registered

- Component
- Dosage
- Shelf Life
- Sterility
- Manufacturer
- Formulation
- Starting Material

Formulation Information			
Active ingredient(s)			
Ingredient name	Qty from	Qty to	Unit
lactic acid	50		mg/g
urea	100		mg/g
Excipient ingredient(s)			
Ingredient name	Qty from	Qty to	Unit
betaine monohydrate	50		mg/g
cholesterol	10		mg/g
diolamine cetyl phosphate	25		mg/g
glyceryl monostearate	100		mg/g
Hard fat	10		mg/g
purified water	0		QS
sodium chloride	5		mg/g

TGA eBS Component

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Product: 807422 CALMURID cream tube
 Component: 514923
 Therapeutic type: Medicine Registered

- Component
- Dosage
- Shelf Life
- Sterility
- Manufacturer
- Formulation
- Starting Material

Dosage Information	
Dosage Form:	Cream
Route of Admin:	Topical
Visual Identification:	Cream (white)

TGA eBS Registration Cancelled

ARTG Entry: 14462 CALMURID cream tube
 Sponsor: 17804 Galderma Australia Pty Ltd
 Therapeutic type: Medicine Registered
 Entry start date: 05/09/1991
 Entry cancel date: 29/05/2020
 Reason: Cancelled by Sponsor
 Code Stock: No
 Evaluation area: Non-Prescription Medicines

- Sponsor
- Agent
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- Financials
- Products
- Manufacturers
- Standards

Manufacturers Information					
Current Manufacturers					
Name	Id	Start date	Certificate / GMP Reference	GMP Status	Principal Manufacturer
Laboratoires Galderma	18986	08/02/2018	M-2016-CL-12914-1	Expired	
Ceased Manufacturers					
Name	Id	Start date	Ceased date		
S22					



Australian Government
Department of Health
Therapeutic Goods Administration

s22

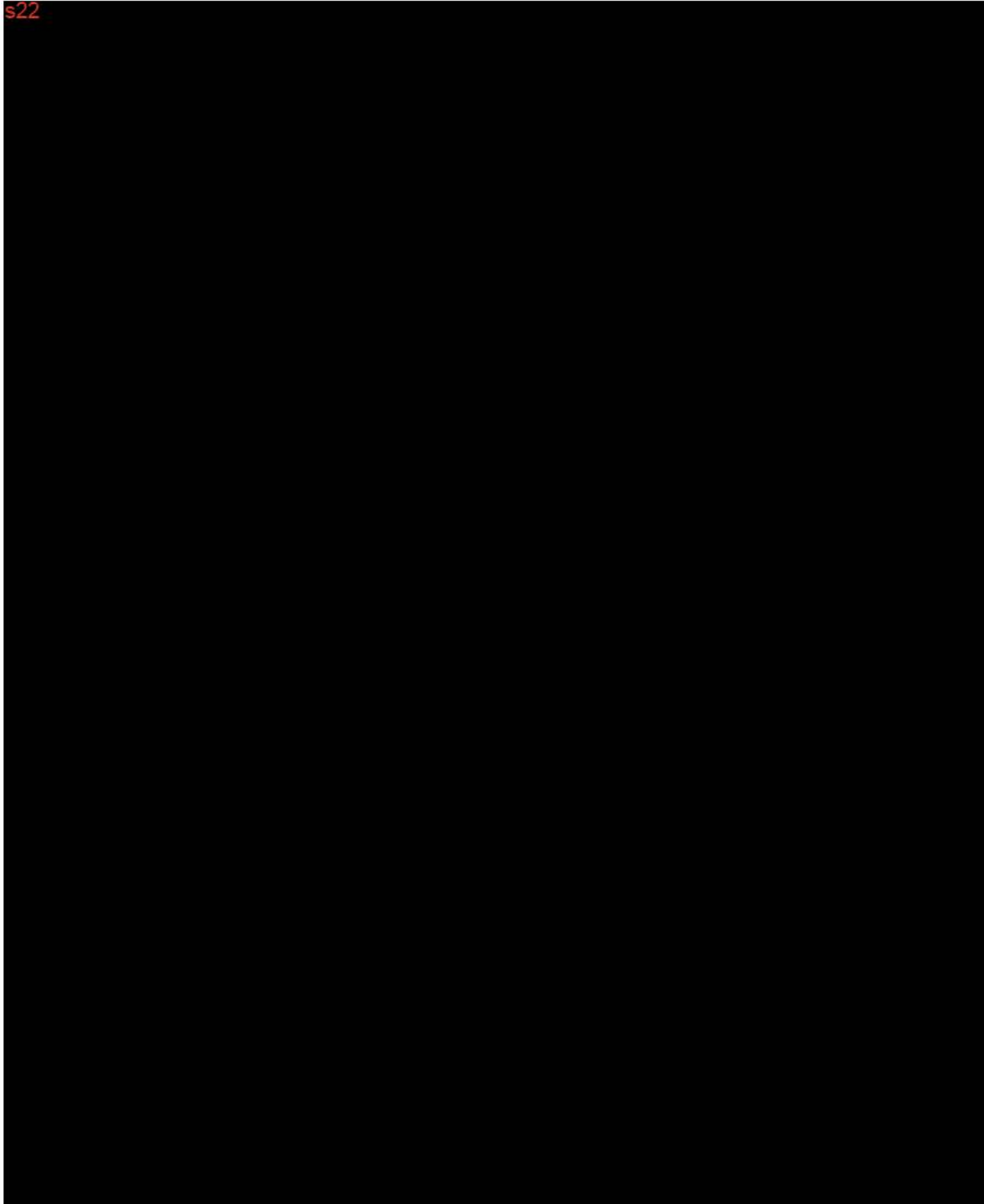


Label changes

Change code	Details	Evaluator comments
s22		
LSR	<p>Addition of more restrictive, safety-related statements:</p> <ul style="list-style-type: none">- <i>Hypersensitivity to the active substance or to any of the excipients of the product.</i> <i>The product should not be extensively used in subjects with severe renal impairment.</i> <i>Avoid contact with the eyes and surrounding area and do not apply the preparation on inflamed skin or open wounds.</i> <i>The product can cause smarting if applied to raw areas, fissures or mucous membranes.</i>- <i>Caution: Urea may enhance the penetration of other active substances into the skin.</i> <i>This is particularly well-known for corticosteroids, dithranol and 5-fluoruracil.</i> <i>In breast-feeding women the product should be removed from the breast area before breast feeding.</i>	<p>Some rewording of the warning statements is required - see notes below.</p>

Change code	Details	Evaluator comments
IHN	Excipient ingredient diethanolamine cetyl phosphate complex (DEA-cetyl phosphate) updated on the labelling to diolamine cetyl phosphate complex	Acceptable
LSP	Update to sponsor logo	Acceptable, <u>need to add change code</u>

s22



s22

