

16/07/2025

Summary view of ARTG# 438851

 **ARTG Name:** NITROSTAT Glycerol trinitrate 400 microgram sublingual tablet bottle (AUST R 438851)

Sponsor Name: **Viatris Pty Ltd** 

Therapeutic type: **Medicine**

License product category: **Registered**

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Current Products

 **Product:** NITROSTAT Glycerol trinitrate 400 microgram sublingual tablet bottle 

Product type: **Single Medicine Product**

Pack size: **Poison info:**

100 sublingual tablets (4 x 25)

(S3) Pharmacist Only Medicine

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Dosage form: Tablet

Visual Id: Small, round, white, tablet debossed with "4" on one side and "N" on the other side

Route of Admin: Sublingual

Active Formulations

 **glyceryl trinitrate 400 microgram**

Excipient Formulations

 **lactose monohydrate** 

 **colloidal anhydrous silica** 

 **lactose monohydrate** 

 **colloidal anhydrous silica** 

 **glyceryl monostearate** 

 **calcium stearate** 

 **pregelatinised starch** 

Summary view of ARTG# 438870

 **ARTG Name:** NITROSTAT Glyceryl trinitrate 300 microgram sublingual tablet bottle (AUST R 438870)

Sponsor Name: **Viatris Pty Ltd -s47**

Therapeutic type: **Medicine**

License product category: **Registered**

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Summary view of ARTG# 11086

 ARTG Name: ANGININE glyceryl trinitrate 600microgram tablet bottle (AUST R 11086)

Sponsor Name: Arrotex Pharmaceuticals Pty Ltd -**s47**

Therapeutic type: Medicine

License product category: Registered

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Current Products

 **Product:** Anginine Tablets (50710)

Product type: Single Medicine Product

Pack size: Poison info:

100 tablets (S3) Pharmacist Only Medicine

30 tablets (S3) Pharmacist Only Medicine

File reference: **s47**

 **Component:** Medicine Component **s47**

Dosage form: Tablet, uncoated

Visual Id: Square flat white to off-white tablet scored on one face and plain on the other face.

Route of Admin: Sublingual

Active Formulations

 glyceryl trinitrate 600 microgram

Excipient Formulations

 glycerol **s47**

 magnesium stearate **s47**

 wheat starch **s47**

 lactose monohydrate **s47**

 dextrin **s47**

 mannitol **s47**

16/07/2025

Summary view of ARTG# 227783

 ARTG Name: ANGININE glyceryl trinitrate 600microgram tablet bottle (AUST R 227783)

Sponsor Name: Arrotex Pharmaceuticals Pty Ltd -**s47**

Therapeutic type: Medicine

Licence product category: Registered

Active Manufacturers

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Current Products

 **Product:** ANGININE glyceryl trinitrate 600microgram tablet bottle (432833)

Product type: Single Medicine Product

Pack size:

Poison info:

100 tablets

(S3) Pharmacist Only Medicine

30 tablets

(S3) Pharmacist Only Medicine

File reference:

 **Component:** Medicine Component (360980)

Dosage form: Tablet, uncoated

Visual Id: Small, round white tablets, with break line on one side and plain on the other side

Route of Admin: Sublingual

Active Formulations

 glyceryl trinitrate 600 microgram

Excipient Formulations

 glycerol **s47**

 magnesium stearate **s47**

 lactose monohydrate **s47**

 dextrin **s47**

 mannitol **s47**

 pregelatinised maize starch **s47**



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Viatris Pty Ltd

for approval to supply

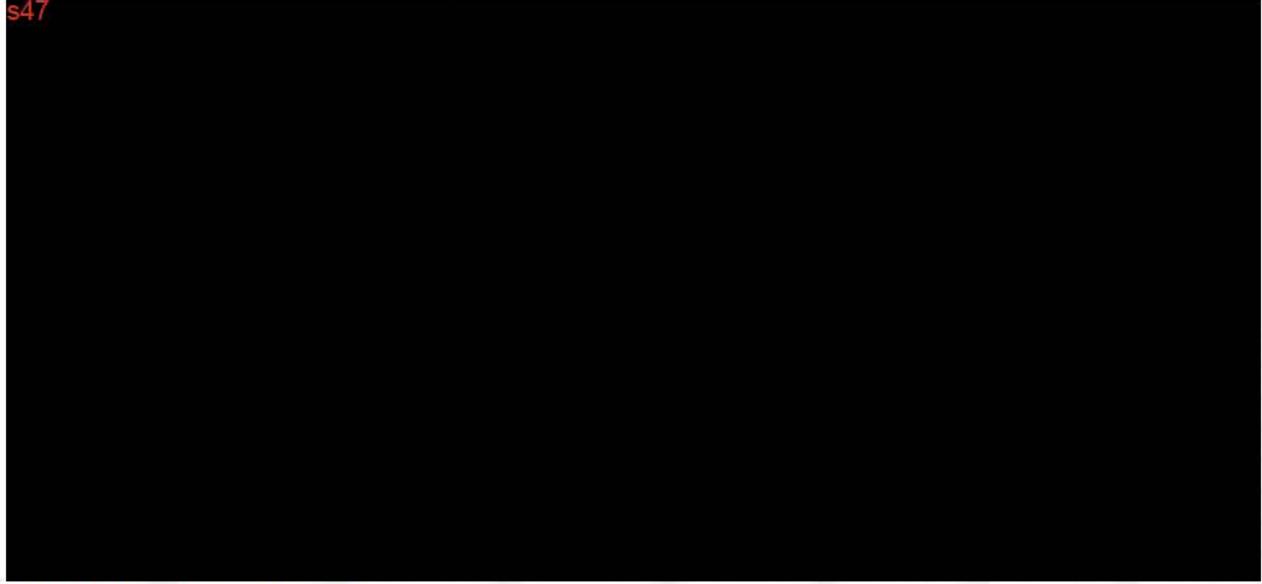
NITROSTAT Glyceryl trinitrate 400 microgram sublingual tablet bottle

ARTG Identifier AUST R 438851

ARTG Start Date 30/06/2025

Product Type Registered Medicine

s47



ARTG Standard Conditions

The above Medicine Registered has been entered on the Register subject to the following conditions:

- 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.
- 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.

Products Covered by This Entry

1. NITROSTAT Glyceryl trinitrate 400 microgram sublingual tablet bottle

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Bottle	Glass Type I Coloured	Closed	Neither child resistant closure nor restricted flow insert	36 Months	Store below 25 degrees Celsius	Protect from Moisture Store in Original Container Protect from Light

s47



Product Permitted Indications

No permitted indications have been recorded against this entry.

Product Indication Requirements

No indication requirements have been recorded against this entry.

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Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- NITROSTAT is indicated for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

Warnings

See Product Information and Consumer Medicine Information for this product.

Dosage Form

- Tablet

Route of Administration

- Sublingual

Visual Identification

- Small, round, white, tablet debossed with "4" on one side and "N" on the other side

Additional Product Information

Product Formulation(s)

Active Ingredients

	Quantity	Units
glyceryl trinitrate	400	microgram

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 438851
ARTG Start Date: 30/06/2025



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Viatris Pty Ltd

for approval to supply

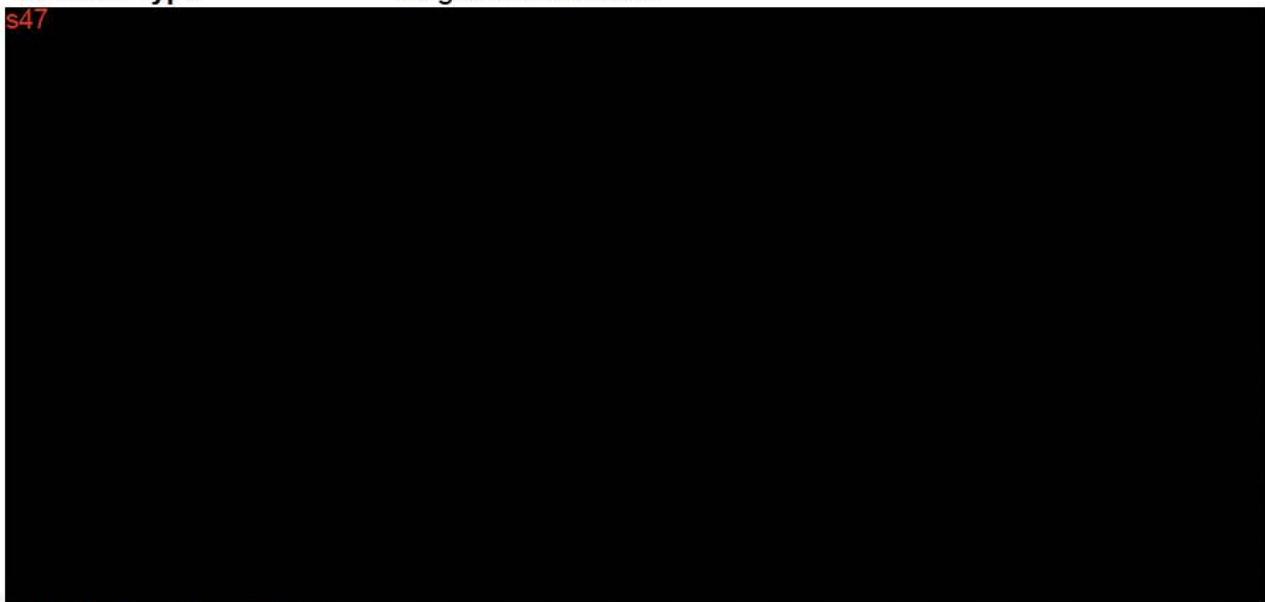
NITROSTAT Glyceryl trinitrate 300 microgram sublingual tablet bottle

ARTG Identifier AUST R 438870

ARTG Start Date 30/06/2025

Product Type Registered Medicine

s47



ARTG Standard Conditions

The above Medicine Registered has been entered on the Register subject to the following conditions:

- 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.
- 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.

Products Covered by This Entry

1. NITROSTAT Glyceryl trinitrate 300 microgram sublingual tablet bottle

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Bottle	Glass Type I Coloured	Closed	Neither child resistant closure nor restricted flow insert	36 Months	Store below 25 degrees Celsius	Store in Original Container Protect from Moisture Protect from Light

s47



Product Permitted Indications

No permitted indications have been recorded against this entry.

Product Indication Requirements

No indication requirements have been recorded against this entry.

Document 6

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- NITROSTAT is indicated for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

Warnings

See Product Information and Consumer Medicine Information for this product.

Dosage Form

- Tablet

Route of Administration

- Sublingual

Visual Identification

- Small, round, white, tablet debossed with "3" on one side and "N" on the other side

Additional Product Information

Product Formulation(s)

Active Ingredients

	Quantity	Units
glyceryl trinitrate	300	microgram

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 438870
ARTG Start Date: 30/06/2025



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

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for approval to supply

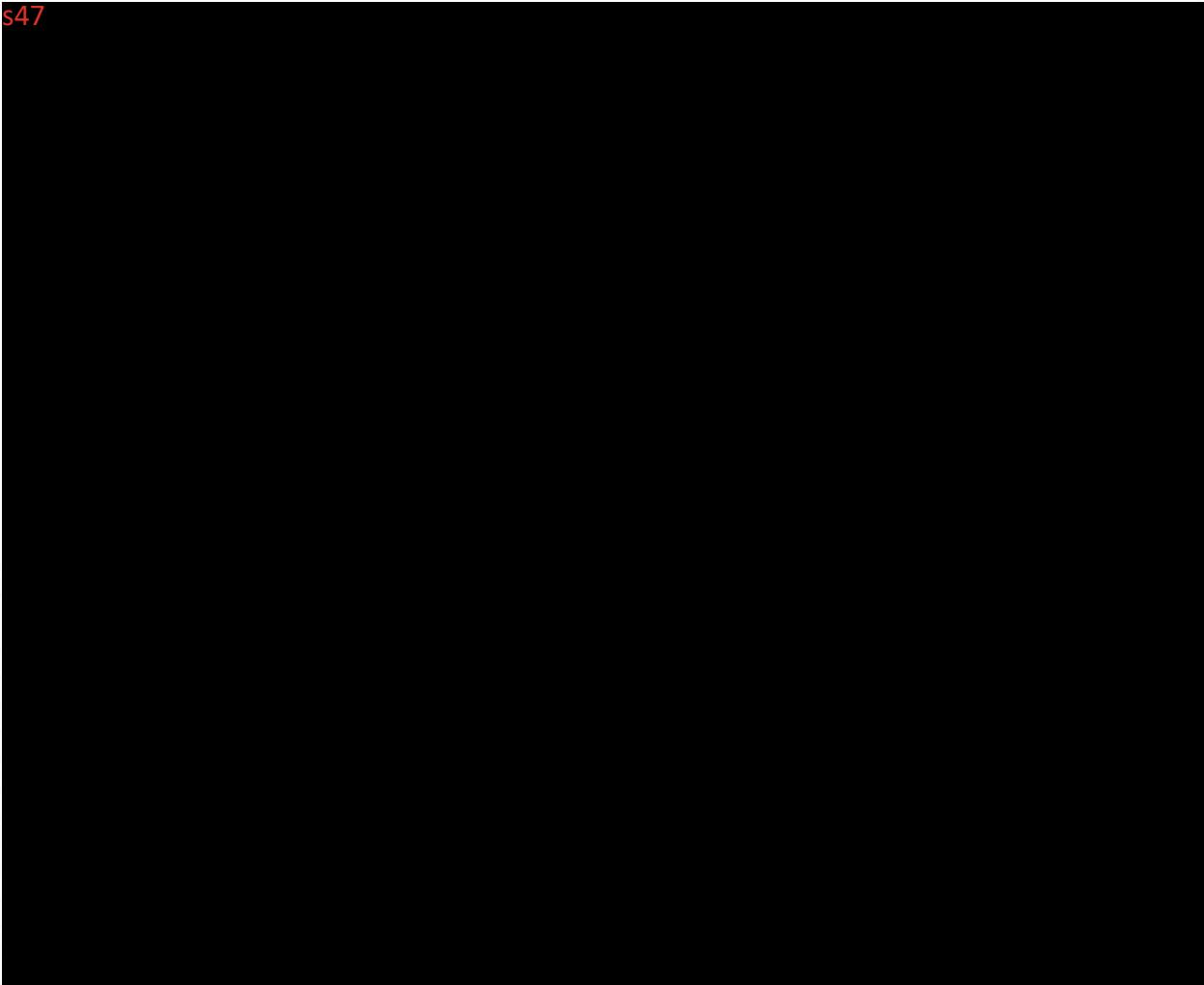
Anginine Tablets

ARTG Identifier AUST R 11086

ARTG Start Date 2/08/1991

Product Type Registered Medicine

s47



ARTG Standard Conditions

The above Medicine Registered has been entered on the Register subject to the following conditions:

- 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"
- 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.
- 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.

Products Covered by This Entry

1. Anginine Tablets

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions	Document 7
Bottle	Glass	Not recorded	Not recorded	2 Years	Store below 25 degrees Celsius	Protect from Light	

s47

Product Permitted Indications

No permitted indications have been recorded against this entry.

Product Indication Requirements

No indication requirements have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- Treatment of acute angina pectoris. As well as relieving the pain of an acute attack, it may be used prophylactically before physical exertion or mental stress which would be expected to produce an anginal attack.

Warnings

No warnings have been recorded against this entry.

Dosage Form

- Tablet, uncoated

Route of Administration

- Sublingual

Visual Identification

- Square flat white to off-white tablet scored on one face and plain on the other face.

Additional Product information

Product Formulation(s)

Active Ingredients

	Quantity	Units
glyceryl trinitrate	600	microgram

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 11086
ARTG Start Date: 2/08/1991



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Arrotex Pharmaceuticals Pty Ltd

for approval to supply

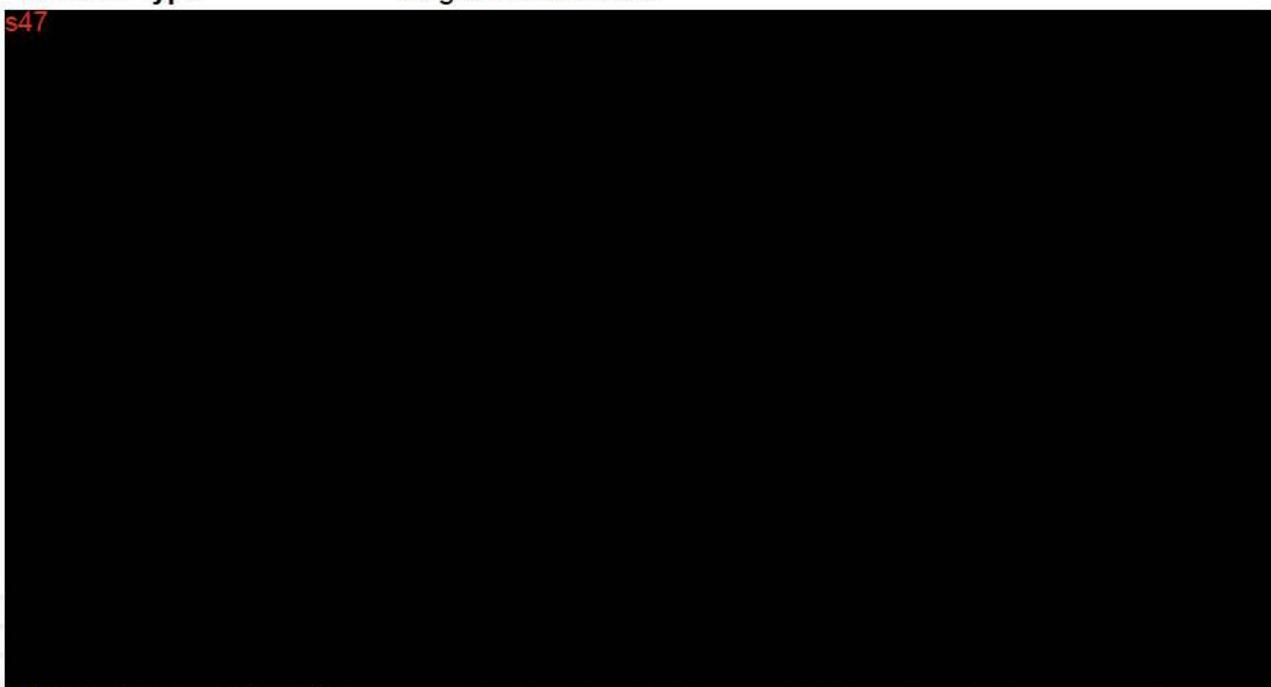
ANGININE glyceryl trinitrate 600microgram tablet bottle

ARTG Identifier AUST R 227783

ARTG Start Date 19/02/2015

Product Type Registered Medicine

s47



ARTG Standard Conditions

The above Medicine Registered has been entered on the Register subject to the following conditions:

- 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"
- 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.
- 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.

Products Covered by This Entry

1. ANGININE glyceryl trinitrate 600microgram tablet bottle

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Bottle	Glass	Not recorded	Not recorded	2 Years	Store below 25 degrees Celsius	Protect from Light

s47



Product Permitted Indications

No permitted indications have been recorded against this entry.

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Product Indication Requirements

No indication requirements have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- Treatment of acute angina pectoris. As well as relieving the pain of an acute attack, it may be used prophylactically before physical exertion or mental stress which would be expected to produce an anginal attack.

Warnings

See Product Information and Consumer Medicine Information for this product.

Dosage Form

- Tablet, uncoated

Route of Administration

- Sublingual

Visual Identification

- Small, round white tablets, with break line on one side and plain on the other side

Additional Product information

Product Formulation(s)

Active Ingredients

	Quantity	Units
glyceryl trinitrate	600	microgram

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 227783
ARTG Start Date: 19/02/2015