



16/07/2025

Summary view of ARTG# 438851

 **ARTG Name:** NITROSTAT Glyceryl trinitrate 400 microgram sublingual tablet bottle ( AUST R 438851 )  
**Sponsor Name:** Viatris Pty Ltd   
**Therapeutic type:** Medicine  
**Licence product category:** Registered



   
   
 
















 

**Current Products**

 **Product:** NITROSTAT Glyceryl trinitrate 400 microgram sublingual tablet bottle   
**Product type:** *Single Medicine Product*  
**Pack size:** *100 sublingual tablets (4 x 25)* **Poison info:** *(S3) Pharmacist Only Medicine*

   
   
**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**






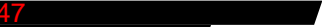























-  *glyceryl trinitrate 400 microgram*
- Excipient Formulations**
-  *lactose monohydrate* 
-  *colloidal anhydrous silica* 
-  *lactose monohydrate* 
-  *colloidal anhydrous silica* 
-  *glyceryl monostearate* 
-  *calcium stearate* 
-  *pregelatinised starch* 





16/07/2025

Summary view of ARTG# 438870



 **ARTG Name:** NITROSTAT Glyceryl trinitrate 300 microgram sublingual tablet bottle ( AUST R 438870 )  
**Sponsor Name:** Viatris Pty Ltd -   
**Therapeutic type:** Medicine  
**Licence product category:** Registered

**Current Products**

 **Product:** NITROSTAT Glyceryl trinitrate 300 microgram sublingual tablet bottle   
**Product type:** *Single Medicine Product*  
**Pack size:** *100 sublingual tablets* **Poison info:** *(S3) Pharmacist Only Medicine*

*File reference:*














 **Component:** NITROSTAT Glyceryl trinitrate 300 microgram sublingual tablet bottle   
**Dosage form:** *Tablet*  
**Visual Id:** *Small, round, white, tablet debossed with "3" on one side and "N" on the other side*

*Route of Admin:* **Sublingual**

**Active Formulations**

 *glyceryl trinitrate 300 microgram*



**Excipient Formulations**

 *lactose monohydrate*   
 *colloidal anhydrous silica*   
 *lactose monohydrate*   
 *colloidal anhydrous silica*   
 *glyceryl monostearate*   
 *calcium stearate*   
 *pregelatinised starch* 




16/07/2025

Summary view of ARTG# 11086

 **ARTG Name:** ANGININE glyceryl trinitrate 600microgram tablet bottle ( AUST R 11086 )  
**Sponsor Name:** Arrotex Pharmaceuticals Pty Ltd -   
**Therapeutic type:** Medicine  
**Licence product category:** Registered















**Current Products**

 **Product:** Anginine Tablets (50710)  
**Product type:** **Single Medicine Product**  
**Pack size:** 100 tablets **Poison info:** (S3) Pharmacist Only Medicine  
30 tablets (S3) Pharmacist Only Medicine

**File reference:** 

 **Component:** Medicine Component   
**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   
 magnesium stearate   
 wheat starch   
 lactose monohydrate   
 dextrin   
 mannitol 





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 -   
**Therapeutic type:** Medicine  
**Licence product category:** Registered


**Active Manufacturers**


**Current Products**

 **Product:** ANGININE glyceryl trinitrate 600microgram tablet bottle (432833)  
**Product type:** Single Medicine Product  
**Pack size:** 100 tablets      **Poison info:** (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   
 magnesium stearate   
 lactose monohydrate   
 dextrin   
 mannitol   
 pregelatinised maize starch 







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

# Australian Register of Therapeutic Goods Certificate

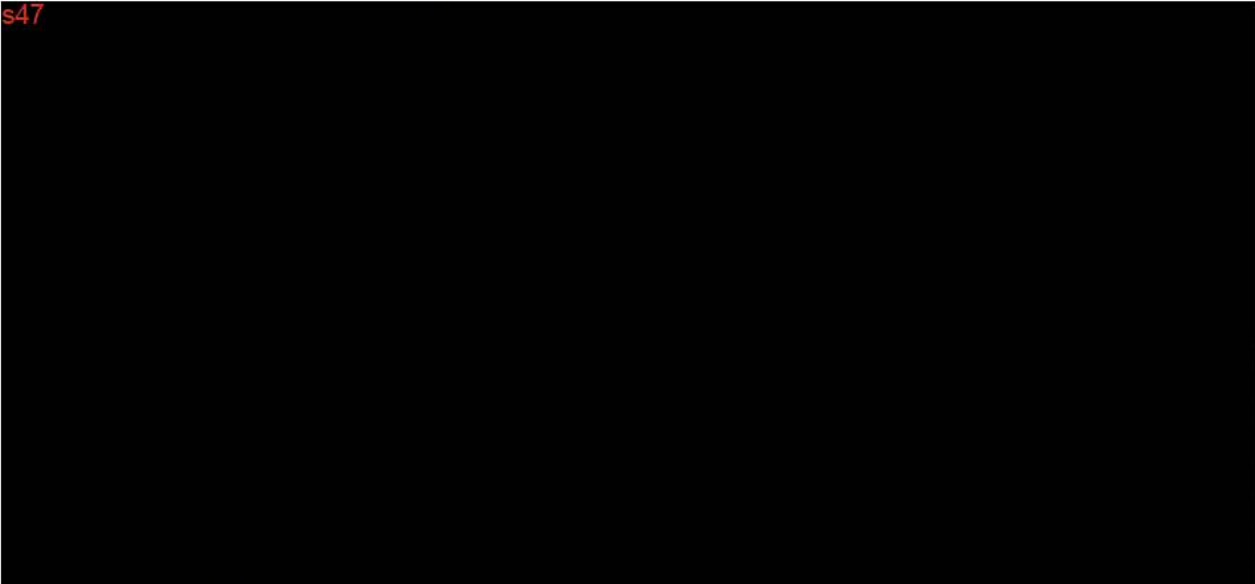
Issued to

**Viatri s 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



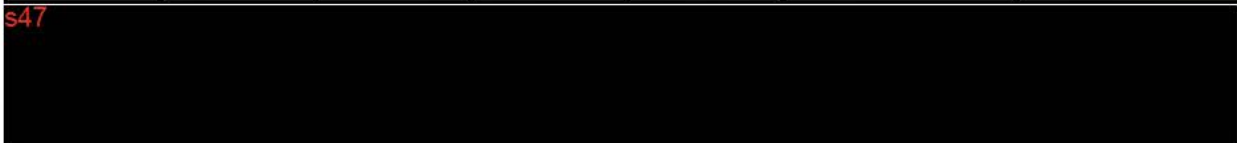
### ARTG Standard Conditions

- 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<br>Type I<br>Coloured | Closed              | Neither child resistant closure nor restricted flow insert | 36 Mont<br>hs   | Store below 25 degrees Celsius | Protect from Moisture Store in Original Container Protect from Light |



### 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](mailto:info@tga.gov.au)

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



Australian Register of Therapeutic Goods Certificate

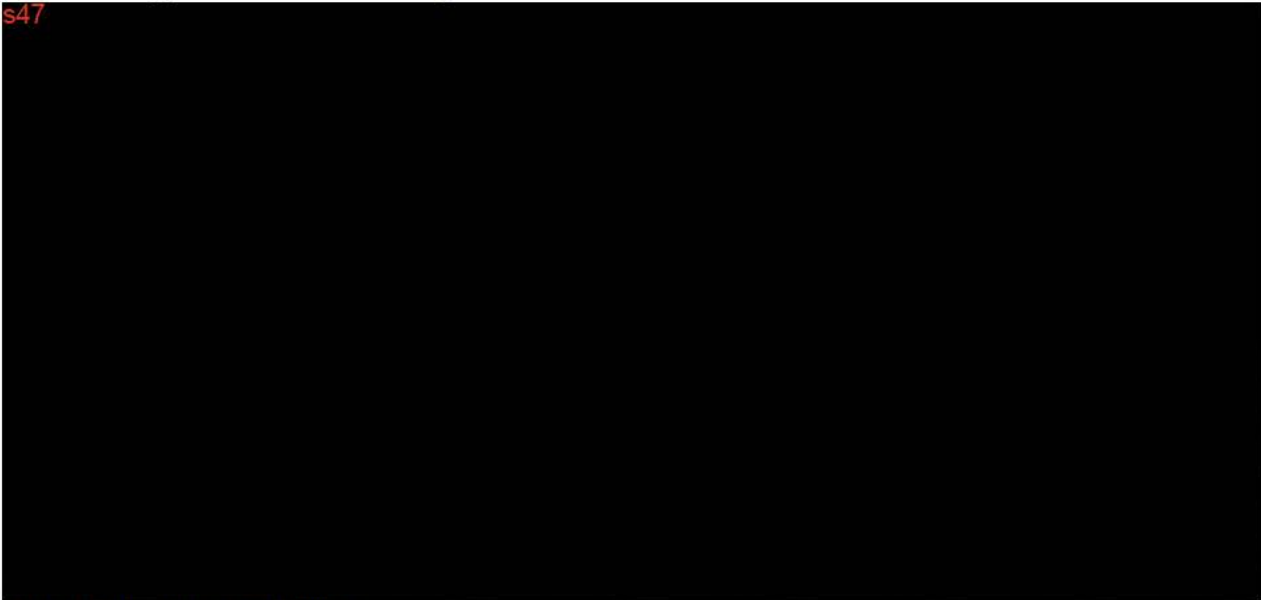
Issued to

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



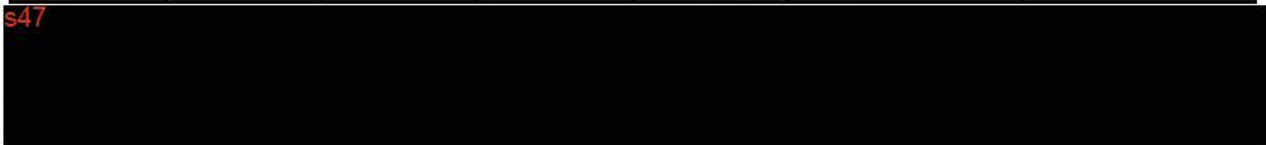
ARTG Standard Conditions

- 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<br>Type I<br>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 |



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](mailto: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

Issued to

**Arrotex Pharmaceuticals Pty Ltd**

for approval to supply

**Anginine Tablets**

|                        |                     |
|------------------------|---------------------|
| <b>ARTG Identifier</b> | AUST R 11086        |
| <b>ARTG Start Date</b> | 2/08/1991           |
| <b>Product Type</b>    | Registered Medicine |

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## 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 |
|----------------|--------------------|---------------------|-------------------|-----------------|--------------------------------|-----------------------|
| Bottle         | Glass              | Not recorded        | Not recorded      | 2 Years         | Store below 25 degrees Celsius | Protect from Light    |

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#### 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](mailto: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

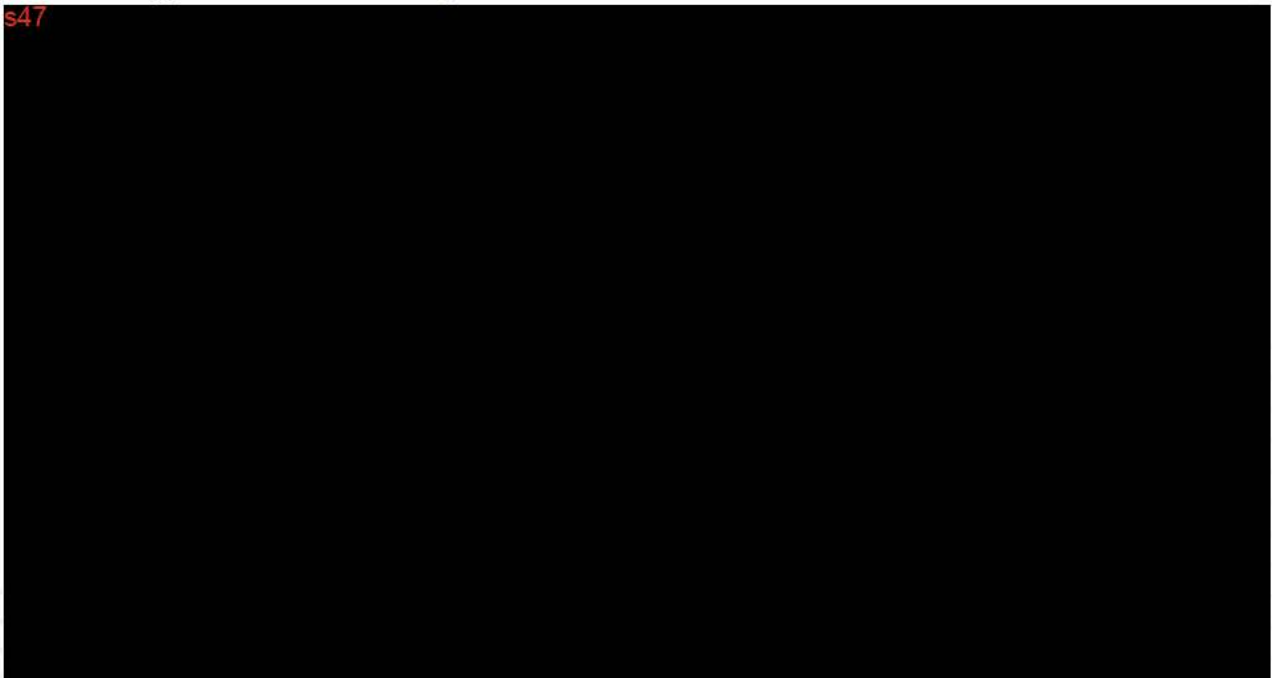
Issued to

**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



## 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    |



## 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**

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](mailto:info@tga.gov.au)

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