



Safety Notice 003/17

8 February 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulations and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Ambulance NSW
- Directors of Emergency Departments
- Directors of Medical Services
- Directors of Nursing & Midwifery
- Directors of Cardiac Services / Cardiology
- Directors of Pharmacy

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Chief Pharmacist Unit
- CEC

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Glyceryl trinitrate (GTN) tablets - disruption to supply

Background

Glyceryl trinitrate (GTN) tablets are used to treat acute angina pectoris (chest pain caused by coronary heart disease). To be effective, they must be placed under the tongue. Use of the tablets is widespread and includes acute healthcare settings, such as hospitals and ambulance services, as well as by patients living in the community. These tablets are marketed in Australia by Arrow Pharmaceuticals under the brand names of Anginine[®] and Lycinate[®].

Anginine[®] and Lycinate[®] share the same formulation. A new formulation was introduced in 2015. The new formulation takes longer to disintegrate than the previous formulation and the tablets are now more difficult to break in half¹. If a GTN tablet does not dissolve properly or quickly enough, the patient may not receive adequate or timely therapy, which could lead to serious health consequences. Arrow pharmaceuticals is working to reformulate the product.

Due to the reformulation process, Anginine[®] and Lycinate[®] are in short supply. Supply is expected to resume after 30 April 2017 for Lycinate[®] and 18 July 2017 for Anginine[®]. Pfizer Australia has been able to arrange supply of an alternate product, Nitrostat[®] on a temporary basis under *section 19A of the Therapeutic Goods Act 1989* until 31 July 2017. Nitrostat[®] has been listed on the Pharmaceutical Benefits Scheme (PBS) and is now currently available for ordering. Supply however will be initially constrained until the end of February to maintain an equitable distribution of stock across Australia.

The spray-based formulation of GTN, marketed as Nitrolingual Pump Spray remains available and can be used where clinically appropriate. The spray delivers a different dose (400 microg) to the tablet forms (600 microg/300 microg).

Although Nitrostat[®] contains the same active ingredient as Anginine[®] and Lycinate[®], and is administered in the same manner; there are a number of differences between the products (refer to point 4 of the *Suggestion actions* below).

Further Information

1. Therapeutic Goods Administration, 3 February 2017 Glyceryl trinitrate tablets (Anginine and Lycinate) <https://www.tga.gov.au/alert/glyceryl-trinitrate-tablets>

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to all stakeholders and all clinical departments.
2. Minimise potential risk when using Anginine[®] and Lycinate[®]
 - a. Prior to putting a tablet under the patient's tongue, provide patients with a mouthful of water to moisten the mouth. This will help dissolve the tablet
 - b. If half a tablet is required, use a pill cutter
 - c. Closely monitor patients when administering the new formulation of Anginine[®] and Lycinate[®] tablets
 - d. If the clinical response is delayed, seek advice from medical staff and report the incident to clinical governance
 - e. Advise relevant patients of this issue and ensure they have understood what actions they should take to minimise any harm from the new formulation.
3. Ensure that only required quantities of Nitrostat[®] are ordered during the supply constraint period
4. Ensure that staff and patients are made aware of the differences between Nitrostat[®] and Anginine[®]/Lycinate[®]
 - a. Nitrostat[®] will be available in both 300 microgram and 600 microgram tablets.
 - b. Differences in the formulation and appearance: Anginine[®] and Lycinate[®] tablets are scored and can be cut in half. Nitrostat[®] **cannot** be cut in half.
 - c. A total of three Nitrostat[®] tablets can be taken over 15 minutes (compared with a total of two for Anginine[®] and Lycinate[®] over 10 minutes).
5. Nitrostat[®] Patient Information is available in each pack of Nitrostat[®] and should be used by clinicians to explain the differences between the product and Anginine[®]/Lycinate[®]
6. Establish a system locally to monitor and document actions taken.