



Safety Notice 002/16

Glyceryl trinitrate (GTN) tablets

03 June 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Chief Health Officer Ministry of Health
- Agency for Clinical Innovation
- Emergency Care Institute
- NSW TAG
- Ambulance NSW

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

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

Expert Reference Group

Content reviewed by:

- CEC
- Ministry of Health
- Pharmaceutical Services

Clinical Excellence Commission

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Internet Website:
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date
September 2016

Background

Glyceryl trinitrate (GTN) tablets, which are given under the tongue, are used to treat acute angina pectoris (chest pain caused by coronary heart disease). Use of the tablets is widespread and includes acute healthcare settings, such as hospitals and ambulances, as well as patients in the community. These tablets are sold under the brand names of Anginine and Lycinatate.

Both Anginine and Lycinatate share the same formulation, including the new formulation that is available in a circular tablet (the old formulation was a square tablet).

Issue

The TGA are advising consumers and health professionals that reports have been received that the new formulation of the glyceryl trinitrate (GTN) tablets is taking longer than expected to dissolve under some patients' tongues.

If a GTN tablet does not dissolve properly or quickly enough, the patient may not receive adequate or timely therapy, which could lead to other serious health consequences.



The TGA is working with the current sponsor, Arrow Pharmaceuticals and the previous sponsor, Aspen Pharma, to investigate this issue.

Minimising risk with the new formulation

1. Provide patients with a mouthful of water to moisten mouth, prior to putting a GTN tablet under their tongue to help it dissolve.
2. If half a tablet is required use a pill cutter.
3. Closely monitor patients when administering the new formulation of GTN tablets.
4. If the clinical response is delayed seek advice from medical staff and report the incident to clinical governance.
5. Advise relevant patients of this issue.

Suggested actions by Local Health Districts/Networks

1. Identify whether the new formulation of GTN tablets is in use.
2. If so, forward this safety notice and the link to the TGA website (below) to appropriate areas for action.
3. Establish a system locally to monitor and document actions taken.

Further information is available on the TGA website at:

<https://www.tga.gov.au/alert/glyceryl-trinitrate-tablets-anginine-and-lycinatate>