



# Safety Notice 021/18

## Discontinuation of nifedipine (twice daily products) and patient safety risks with alternative

**18 December 2018**

**Distributed to:**

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

**Action required by:**

- Chief Executives
- Directors of Clinical Governance

**We recommend you also inform:**

- Head of Maternity Services
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing and Midwifery
- Drug and Therapeutics Committee

**Expert Reference Group**

Content reviewed by:

- Office of the Chief Health Officer, MoH
- Chief Pharmacists Unit, MoH
- HealthShare NSW
- Director Patient Safety

**Clinical Excellence Commission**

Tel. 02 9269 5500  
Fax. 02 9269 5599

Email: [CEC-MedicationSafety@health.nsw.gov.au](mailto:CEC-MedicationSafety@health.nsw.gov.au)

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

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

**Review date**

December 2019

**Background**

Nifedipine (Adalat® and Adefin®) 20mg twice daily tablets and the nifedipine (Adalat®) 10mg twice daily tablet have been discontinued in Australia. **The Adefin® brand of nifedipine 10mg twice daily tablet is still available and can be purchased from wholesalers.**

Nifedipine is available as once, twice and three times daily oral formulations. They have varying naming conventions for the tablets which increase the risk of inadvertent administration of the wrong formulation.

Examples of once daily formulations include Adalat Oros®, Adefin XL® and Addos XR® which have been referred to as extended release, controlled release, modified release or mediated release tablets. Examples of twice daily formulations include Adalat® and Adefin®, which in Australia have been referred to as immediate release or conventional tablets. Imported products may be referred to as modified release, retard or biphasic tablets. Three times daily formulations have not been registered in Australia for many years. They were previously available as Adalat® capsules and referred to as short acting or immediate release forms.

Nifedipine is indicated for hypertension and angina. In NSW, the nifedipine twice daily oral product is also the first line agent for tocolysis and second line agent for hypertension in pregnancy.

Previously, all nifedipine 10mg and 20mg twice daily oral products had been reported to be discontinued. Consequently, the Therapeutic Goods Administration authorised temporary supply of nifedipine 10mg three times daily capsules (Nifedipine AL 10®, Germany) under Section 19A of the Therapeutic Goods Act 1989. This has now lapsed with nifedipine 10mg twice daily tablets (Adefin®) back in stock.

Nifedipine three times daily capsules are absorbed more rapidly than once and twice daily products, placing patients at increased risk of uncontrolled reductions in blood pressure. Hospital wide strategies to prevent inadvertent administration of the wrong formulation should be implemented before any use is authorised.

**Further Information**

Please email [HSNSW-HSCPM@health.nsw.gov.au](mailto:HSNSW-HSCPM@health.nsw.gov.au) for supply options.

**Suggested actions by Local Health Districts/Networks**

- 1 Ensure that this safety information is distributed to all clinical staff involved in the prescribing, administration, dispensing or supply of medicines.
- 2 Prescribers, nurses, midwives and pharmacy staff should be made aware of the different formulations and their appropriate use.
- 3 **Nifedipine 10mg twice daily tablets should continue to be used for tocolysis and hypertension in pregnancy, in preference to Section 19A stock of nifedipine three times daily capsules.**
- 4 **Use of nifedipine 10mg three times daily capsules should be minimized. If use is necessary, facilities should ensure that guidelines and medication safety strategies are in place before use is authorised. Medication Safety strategies should include:**
  - a. Restrict use of the nifedipine 10mg three times daily capsule to only tocolysis and hypertension in pregnancy.
  - b. If it is necessary to stock nifedipine on maternity and birthing unit imprests, stock only one formulation. Highlight whether it is the nifedipine twice or three times daily formulation and communicate this information to clinicians.
  - c. Guidelines for the correct use and monitoring of the three times daily oral formulation should be made available and communicated to clinicians.
  - d. Prescribers should clearly specify the strength and formulation on the National Inpatient Medication Chart or select the correct formulation in the electronic medication management system (consider use of electronic prompts/warnings).
- 5 Ensure a system is in place to document actions taken.