



Safety Notice 001/21

Discontinuation of nifedipine immediate release products (update)

18 January 2021

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:

- Nifedipine Working Group
- Medication Safety Expert Advisory Committee

Clinical Excellence Commission

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

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

Review date

January 2022

Background

Nifedipine is a dihydropyridine calcium channel blocker most commonly used to treat hypertension and angina. It is also used off-label as a tocolytic in pre-term labour. Oral formulations can be given once, twice or three times daily depending on their duration of action.

The supply of nifedipine in a safe, consistent and appropriate formulation remains a concern. It is critical that nifedipine products are assessed for the intended frequency of administration (through verification with the Product Information), prior to being made available for patient use.

In NSW, the nifedipine **immediate release tablet (medium acting)** is the preferred first line agent for tocolysis and is also commonly used for acute hypertension in pregnancy^{1,2}.

Nifedipine modified release tablet (long acting), is recommended for treatment of preeclampsia, gestational or chronic hypertension in pregnancy¹.

Internationally, these formulations have varying naming conventions which increases the risk of inadvertent administration of the wrong formulation. For example, products referred to as 'modified/controlled/slow release' tablets in Australia are long acting and administered once daily, while internationally this may refer to tablets which are medium acting.

Adalat® and Adefin® medium acting tablets have been discontinued in Australia, however Nifelat® 10 mg medium acting tablets are available through the Special Access Scheme (SAS).

Nifedipine **immediate release capsules (short acting)** are also available via the SAS. The capsules are absorbed more rapidly than tablets. This puts patients at increased risk of sudden reductions in blood pressure.

Note: Nifedipine medium acting **tablets are preferred** to short acting **capsules**.

The following table summarises the nifedipine formulations currently available in Australia.

Nifedipine Formulation	Duration of action	Frequency of administration (for hypertension**)	Availability	Products available as of January 2021
Modified release tablets* (30 mg, 60 mg) <i>Note: 20mg modified release tablets were recently discontinued</i>	Long acting	Once daily	Registered for use in Australia, available from wholesalers.	Adalat Oros, Addos XR, Adefin XL, APO
Immediate release tablets (10 mg)	Medium acting	Twice daily	Not registered for use in Australia.	Nifelat
Immediate release capsules (10 mg)	Short acting	Three times daily	Available via SAS.	AL, Adalate

*Modified release tablets should not be crushed, broken or chewed.

**More frequent administration is required for tocolysis and acute hypertension in pregnancy

Further Information: For supply options email Noman.Masood@health.nsw.gov.au (HealthShare NSW)

References:

1. Lowe SA, Bowyer L, Lust K, McMahon L, Morton M, North RA, et al. Guideline for the management of hypertensive disorders of pregnancy. Society of Obstetric Medicine of Australia and New Zealand 2014.
2. Urgent control of elevated blood pressure. *eTG complete, Cardiovascular*. Melbourne : Therapeutic Guidelines Limited, March 2018.
3. NSW Ministry of Health. Policy Directive PD2011_064. *Maternity - Management of Hypertensive Disorders of Pregnancy*, 2011.
4. NSW Ministry of Health. Guideline GL2020_009. *Maternity- Management of Threatened Preterm Labour Guideline*, 2020.

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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 nifedipine formulations available and their appropriate use.
3. **Nifedipine medium acting tablets should continue to be used for tocolysis and acute hypertension in pregnancy** in accordance with the [Maternity - Management of Hypertensive Disorders of Pregnancy \(PD2011_064\)](#) and [Maternity- Management of Threatened Preterm Labour Guideline \(GL2020_009\)](#). Nifedipine has a more favourable adverse effect profile and better outcomes for neonates compared with other tocolytics. Prescribers need to obtain written informed consent when prescribing nifedipine to patients for use in tocolysis.
4. **The use of nifedipine short acting capsules should be avoided for tocolysis and acute hypertension in pregnancy.**
5. If the use of nifedipine short acting capsules is necessary (i.e. medium acting immediate release tablet is not available), facilities should implement appropriate medication safety strategies before use is authorised:
 - a. Guidelines for the correct use and monitoring of the nifedipine short acting capsules should be made available and communicated to clinicians.
 - b. Nifedipine short acting capsules should not be routinely available on ward imprests outside of maternity and birthing units.
 - c. Maternity and birthing units should stock only one nifedipine immediate release formulation on imprest. If nifedipine short acting capsules are stocked, highlight and communicate this information to clinicians.
 - d. Prescribers should clearly specify the nifedipine strength and formulation intended, as well as the indication for use in medication orders.
 - e. Consider implementing electronic alerts with relevant safety information if nifedipine short acting capsules are available for use.
6. Facilities should assess their current stock levels of nifedipine immediate release formulations and ensure stock levels are adequate for their expected demand of patients presenting for tocolysis and/or acute hypertension in pregnancy.
7. Ensure a system is in place to document actions taken and to monitor usage.