

# MEMO

Date 11 January 2022



**Health**  
Department for  
Health and Wellbeing

To SA Maternity Care Providers

From Prof Jodie Dodd, Chair, SA Maternity Neonatal Community of Practice

**SA Maternal Neonatal &  
Gynaecology Community of  
Practice**

**WCHN CORPORATE  
GOVERNANCE & POLICY**

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**Subject: INFORMATION re Restricted use of Nifedipine in the pregnant person**

Dear Maternity Care Provider

- You may be aware Nifedipine 10mg immediate release tablets have been discontinued from the Australian market and it is very unlikely another manufacturer will seek registration within Australia.
- You would have routinely utilised Nifedipine 10mg immediate release tablets (B2 receptor agonist) the first line management of threatened premature labour.
- The TGA granted Section 19A approval to import an overseas brand of Nifedipine 10mg immediate release tablets for use in accordance with approved product information (i.e. chronic stable angina pectoris, vasospastic angina or essential hypertension).

Note the current product information contraindicates the use of Nifedipine during pregnancy. The Section 19A approval for Nifedipine does not apply to preterm birth.

- There is uncertainty around the ongoing overseas supply chain for Nifedipine. We have been advised there are now limited suppliers and therefore it may not be available in the long-term. In addition, the products are not labelled in English which poses a medication safety concern. If the medication is secured from overseas stocks provision will need to be taken to ensure the labelling is printed in English prior to distribution.
- Medical Officers can utilise the Special Access Scheme (SAS) to obtain access to restricted supplies of Nifedipine 10mg immediate release tablets for preterm birth through the following pathways:
  - Submission of a Category A SAS application for individual patients, including a patient SAS consent form;
  - The prescriber needs to complete paperwork once for each patient, prior to or soon after first administration
  - Completion of a 19-5 application to become an authorised prescriber
- Nifedipine supplies will be stockpiled. The stock will be allocated to critical sites across SA Health (coordinated in consultation with SA PPG Pharmacy rep Catherine Leggett).
- Atosiban (oxytocin receptor antagonist) is used overseas in the management of preterm labour is available as an intravenous preparation and registered in the UK for management of preterm labour in pregnant women with:
  - regular uterine contractions of at least 30 seconds duration at a rate of  $\geq 4$  per 30 minutes
  - a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of  $\geq 50\%$
  - a gestational age from 24 until 33 completed weeks
  - a normal fetal heart rate
- Atosiban is currently not marketed in Australia and we understand there has been correspondence to suggest it is quite costly and purchase of the drug would not be commercially viable. However, consideration could be given exploring the [TGA Orphan Drug designation](#).

- The cost of Atosiban is approx. \$1700 for 48 hours IV administration, compared to nifedipine, which is \$20 for 48 hours of oral administration.

Ref:

1. van Vliet. E at al, T Nifedipine versus atosiban for threatened preterm birth (APOSTEL III): a multicentre, randomised controlled trial *The Lancet* 2016 Vol. 387 Issue 10033 Pages 2117-2124 DOI: 10.1016/s0140-6736(16)00548-1
  2. Sean Turner. Director Pharmacy. Portfolio lead / manufacturing and QC/ Training and Research SA pharmacy. SA Health
- The *Preterm Labour and Birth: Prevention, Diagnosis & Management* Perinatal Practice Guideline (PPG) has recently been revised and is now published on both the SA Health website ([www.sahealth.sa.gov.au/perinatal](http://www.sahealth.sa.gov.au/perinatal)) and the SA Practice Guidelines web-based App (<https://extapps2.sahealth.sa.gov.au/PracticeGuidelines/>).

## **RECOMMENDATIONS FOR CLINICAL PRACTICE**

- Given Nifedipine remains the first-line drug of choice for treatment of preterm - continue to use Nifedipine off label as our first line therapy for acute tocolysis.
- Restrict the use of Nifedipine to the following indications only:  
In the management of the woman in preterm labour
  - who is being transferred to a service with level 5 or 6 neonatal facilities.
  - to delay preterm birth and to facilitate administration and action of steroids.
- Use alternative medication options for the treatment of severe pregnancy induced hypertension.
- Tocolysis with Nifedipine is **ONLY** indicated if:
  - The woman is less than 34+6 weeks pregnant and;
  - Requiring transfer to a gestation appropriate maternity service and/or;
  - Yet to complete an initial course of antenatal corticosteroids.
- Do not continue Nifedipine beyond 48 hours. A repeat course of Nifedipine should only be considered if the woman represents with preterm labour.
- Nifedipine is NOT to be used prophylactically.

Please feel free to contact Marnie Aldred, Project Manager, SAPPG Management Committee [marnie.aldred@sa.gov.au](mailto:marnie.aldred@sa.gov.au) – if you require any additional information.

I thank you for your anticipated co-operation.



Prof Jodie Dodd  
Chairperson, SA Maternity Neonatal & Gynaecology Community of Practice Executive Leadership Committee

cc Assoc Prof Chris Wilkinson – Chair SA PPG Management Group  
cc Marnie Aldred – PO SA PPG Management Group