



Issue: Ergometrine Supply

Raised by: Cecile Dye (HCM, Harts Range)

Background: Stocks of Ergometrine 500mcg/mL injection are currently unavailable.

Mayne Pharma Pty Ltd (now Hospira Australia), have notified of manufacturing difficulties with Ergometrine 500mcg/ml inj. This drug has not been available since June 2007, but is expected to be back in production and available by March 2008.

Discussion: Although Ergometrine is less frequently used than previously, it remains an important drug in Obstetric Emergencies in the remote context (it is contained in the Obstetric Drug Kit).

For the interim period, **Methylergometrine 200mcg/ml injection** is the alternative drug available. While this drug is not usually registered for use in Australia, it has short-term TGA approval for use under the Category A Special Access Scheme.

Note: the active ingredient & concentration is NOT the same as Ergometrine.

Where a Health Centre's Ergometrine stock is low or out of date, Methylergometrine should be requested from the Regional Hospital Pharmacy.

As with Ergometrine, use of Methylergometrine is only to be used following consultation with a medical officer. Where applicable, Health Centre staff should advise the consulting Medical Officer that Methylergometrine is currently stocked.

The Medical Officer is required to certify on the [Category A Form](#) that they "**have obtained the informed consent of the patient, or the patient's legal representative**" before they prescribed the drug. DMO's will have this form available when on-call, and are obliged to complete the form whenever Methylergometrine is used. Additionally, in Health Centres, a copy of the blank form should be kept with the Obstetric Drug Kit.

Completed forms are to be submitted to the TGA via the Regional Pharmacy. Pharmacy will not re-issue any further Methylergometrine to the Health Centre until the completed form has been received.

In the event of a suspected adverse drug reaction, following appropriate clinical management, ADRAC (Adverse Drug Reactions Advisory Committee) should be notified using the [ADRAC Report form](#). Additionally, the supplier provides their own '*Adverse Drug Experience Capture Form*' with the drug; this can also be completed and submitted to the company in the event of such a reaction.

Consultation: ASH & RDH Pharmacists; Hospira Australia

References: <http://www.tga.gov.au/docs/pdf/unapproved/sascata.pdf>
<http://www.tga.gov.au/adr/bluecard.pdf>

Outcome: **Methylergometrine 200 mcg/ml injection is the interim alternative to Ergometrine, until Ergometrine is available again (expected late March 2008).**

Specific documentation must be completed by the DMO/GP if the drug is used.

The required forms should be readily available and are to be kept:

- by the DMO on-call

and

- in the Emergency Obstetric Drugs Kit (in the Health Centre)