MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Ergometrine 500 microgram/mL injection – 25 January 2021

Details of affected product(s)	DBL ergometrine maleate 500 microgram/mL injection ampoule – ARTG 58866
Reason for communication	Supply disruption – limited supply may be available (constrained release)
Date issue made apparent	11 January 2021
Estimated resolution date	18 June 2021

Main therapeutic applications

Oxytocic agent used to prevent or treat postpartum haemorrhage.

Alternative agents

- A Canadian registered product (Teligent brand) 0.25 mg/mL (250 microgram/mL) injection (accessible via Link Medical Products P/L) has been approved for limited supply under an exemption granted by the Therapeutic Good Administration under section 19A of the Therapeutic Goods Act 1989.
- Medsurge Healthcare may be available to supply a 500 microgram/mL ergometrine injection product via the Therapeutic Goods Administration's Special Access Scheme. This product is; imported from the UK (Hameln brand), labelled in English and the same strength and concentration as the Australian registered product. Please note – there may be a 15-20 business day lead time on this product.
- A fixed dose combination of ergometrine with oxytocin (Syntometrine®) is also available, if both agents are clinically indicated.
- Refer to Appendix 3 of GL2017_018: Maternity – Prevention, Detection, Escalation and Management of Postpartum Haemorrhage (PPH) for alternative pharmacological agents for the prevention and/or treatment of primary postpartum haemorrhage.

Precautions and safety issues associated with alternative products

- The Teligent brand available from Link is labelled as **ergonovine maleate** (which is the Canadian generic name for ergometrine).
- Additionally, it is a different strength and concentration to the Australian registered product – **0.25 mg/mL (250 micrograms/mL) (Teligent) compared to 500 micrograms/mL (DBL).** Care should be taken to prevent inadvertent underdosing.
- Drug and Therapeutics Committees should review and assess whether there is a local need for; relabelling, strategies to assist product selection and/or education of staff, prior to introduction of this alternative product.
- TGA Safety Information outlining the above was released 21 January 2021.

Impacts of this communication on clinical practice

A S19A alternative is available which can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy issues

PD2013_043 Medication Handling in NSW Public Health Facilities

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au

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