AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

FACT SHEET

for health service organisations and clinicians

Safety considerations during oxytocin injection supply disruption

What you need to know

- There is a shortage of oxytocin injection in Australia.1
- The discontinuation of multiple brands of oxytocin injection from the Australian Register of Therapeutic Goods (ARTG) has increased demand for the available oxytocin injection products.
- The Therapeutic Goods Administration (TGA) has approved alternative products under <u>Section 19A (S19A)</u>:
 - Panpharma, Germany brand which is licensed overseas for both intravenous (IV) and intramuscular (IM) use
 - o Wockhardt, UK brand which is only licensed overseas for IV use.
- In Australia, oxytocin is administered IM for prevention or treatment of postpartum haemorrhage (PPH) following childbirth.²
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has provided advice on the use of the Wockhardt, UK product.
- The <u>oxytocin monograph</u> in the Australian Injectable Drugs Handbook has been updated to provide clinicians with guidance on the approved alternative products under S19A during the shortage.

Purpose

This fact sheet has been developed by the Australia Commission on Safety and Quality in Health Care to assist clinicians to provide safe and quality health care during the <u>oxytocin injection supply</u> disruption in Australia.

Safety considerations

There have been reports of incidents involving administration of pre-prepared oxytocin infusions in place of IV fluids to women in labour, which increases the risk of harm to the woman and the baby.³ In Australia, IM administration of oxytocin remains the standard method for PPH prevention following childbirth. Routine placement of an IV cannula in all birthing women is not recommended, as it could increase procedural interventions and the risk of medication errors.⁴

The <u>Panpharma</u>, <u>Germany</u> brand of oxytocin can be administered via the IM route. If this product is unavailable, the <u>Wockhardt</u>, <u>UK</u> brand can be considered. RANZCOG has provided <u>advice</u> on the use of the Wockhardt, UK product. If IM use is proposed, then local guidelines on off-label use of medicines or the <u>CATAG Guiding Principles for the quality use of off-label medicines</u> should be considered.

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The <u>Australian Injectable Drugs Handbook – Oxytocin monograph</u> has been updated to provide guidance on safety considerations during the shortage.⁵ The updated content includes information on the composition of the S19A products compared with products currently on the ARTG as well as those that have been recently discontinued.

Visit the TGA website for more information on the oxytocin injection supply disruption.

Background

Oxytocin is a synthetic pituitary hormone that stimulates uterine muscle contraction for the induction of labour, management of the third stage of labour, and prevention or treatment of PPH. The Australian registered products can be administered via both IV and IM routes.^{2,5}

The discontinuation of the Viatocinon® and Syntocinon® brands of oxytocin injection has increased demand for the Oxytocin Generic Health (GH) brand, leading to a shortage in Australia. In response, the TGA has approved two overseas products under S19A of the Therapeutic Goods Act 1989. These are the Panpharma, Germany brand, which is licensed overseas for both IV and IM administration and the Wockhardt, UK brand, which is only licensed overseas for IV administration.

Useful resources

Australian Injectable Drugs Handbook – Oxytocin monograph

NICE guideline - Intrapartum care

RANZCOG Management of Postpartum Haemorrhage

RANZCOG Care in labour in the absence of pregnancy complications

RANZCOG statement about the IM use of Oxytocin 10 units in 1mL concentrate for solution for infusion ampoules (Wockhardt, UK)

Rethinking medicines decision-making for off-label use of medicines

TGA Medicine shortage information - Oxytocin

TGA Section 19A approvals database

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References

- Australian Government Department of Health and Aged Care. Oxytocin medicine shortage information. [Internet] Canberra: Australian Government Department of Health and Aged Care; [cited Apr 2025] Available from: https://apps.tga.gov.au/Prod/msi/Search/Details/oxytocin.
- 2. Australian Medicines Handbook. Oxytocin: Australian Medicines Handbook; 2025.
- 3. National Health Service England. Risk of oxytocin overdose during labour and childbirth. Redditch: NHS; 2024.
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists.
 Feedback on the Off-Label Intramuscular Administration of the Wockhardt Oxytocin Alternative, 2025.
- 5. Advanced Pharmacy Australia. Australian Injectable Drugs Handbook Oxytocin: Advanced Pharmacy Australia 2025.

For more information, please visit: <u>TGA Medicine Shortage Reports Database</u> or contact the Commission at medsafety@safetyandquality.gov.au.

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