

Potential for selection errors and harm with misoprostol tablets in maternity services



N SAFETY NOTICE 014/25

Issue date:	19 June 2025
Content reviewed by:	Medication Safety Expert Advisory Committee (MSEAC) Agency for Clinical Innovation (ACI) Maternity and Neonatal Network Health and Social Policy Branch CEC Maternity and Neonatal Safety Improvement Program
Distributed to:	Chief Executives; Directors of Clinical Governance
KEY MESSAGE:	NSW Health facilities are informed of the potential errors associated with different presentations of misoprostol tablets and the associated safety considerations and recommendations.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"> 1. Distribute this Safety Notice to all relevant clinicians and clinical departments where misoprostol tablets are held, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles. 2. Undertake a local risk assessment and incorporate the below recommendations to manage the potential error. 3. Ensure a system is in place to document actions taken in response to this Safety Notice. 4. Report any incidents associated with the use of misoprostol into the local incident management system e.g., ims+.
We recommend you also inform:	<p>Directors, Managers and Staff of:</p> <ul style="list-style-type: none"> • Maternity services, including all inpatient and outpatient units • Anaesthetics and Operating theatres • Emergency Departments • Intensive Care Units • Pharmacy Services • Nursing and Midwifery Services • Medical Services • Electronic Medication Management (eMM) Teams and ICT staff <p>Drug and Therapeutics Committees All other relevant clinicians, departments and committee</p>
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	June 2026

Potential for selection errors and harm with misoprostol tablets in maternity services

N SN: 014/25

Situation

There is a potential for confusion between misoprostol (Angusta) 25 microgram tablets and misoprostol (Cytotec) 200 microgram tablets as they contain the same generic ingredient “misoprostol” and are used in maternity services, which may lead to selection errors.

Background

Misoprostol (prostaglandin E1) is a prostaglandin analogue used for pregnant and/or postnatal women for the following indications:

Misoprostol 25 microgram tablets –

- Induction of labour **at full term** gestations (see NSW Health Policy Directive *Induction of Labour PD2025_019*).

Misoprostol 200 microgram tablets –

- Induction of labour in the context of **termination of pregnancy** and **fetal death in utero** in the second and third trimester
- Medical management of retained products of conception following miscarriage.
- Cervical preparation for surgical management of miscarriage or termination.
- Termination of intra-uterine pregnancy up to 63 days gestation, with mifepristone.
- Maintenance treatment for the management of **postpartum haemorrhage** (PPH) (see NSW Health Guideline *Postpartum Haemorrhage GL2025_005*).

NOTE: Indications for the use of misoprostol 200 microgram tablets outside of maternity services are **not** addressed within this Safety Notice.

Both strengths of misoprostol tablets are listed on the [NSW Medicines Formulary](#) with restrictions (see Appendix 1).

Assessment

Misoprostol 25 microgram tablets were first listed to the NSW Medicines Formulary in February 2024, however due to the recent publication of [PD2025_019](#) and associated Agency for Clinical Innovation (ACI) *Clinical Practice Guideline – Induction of labour: Methods and approaches*, the use of this formulation is expected to increase.

The availability of multiple tablet strengths of misoprostol for use in maternity service areas increases the risk of selection errors during prescribing, dispensing and administration. Administration of an incorrect dose may cause harm to both the woman and/or her fetus.

Therefore, health services must ensure risk mitigation strategies are in place to prevent such errors and should consider adopting a precautionary approach by treating misoprostol as a high-risk medicine.

Recommendations

Ensure clinicians involved in the prescribing, dispensing and administration of misoprostol are aware of the risk of selection error and that local risk mitigation strategies are employed to minimise the risk of selection errors. Strategies may include the following:

Potential for selection errors and harm with misoprostol tablets in maternity services

N SN: 014/25

Prescribing and Electronic Medication Management (eMM) systems configurations

- Due to the high risk of misinterpretation, verbal orders should be avoided where possible. In emergency situations when a verbal order is given, the prescribing and administering clinicians must use a 'closed-loop' communication technique to verify all relevant patient and medicine information prior to administration.
- When prescribing misoprostol within eMM systems, select from pre-built order sentences within eMR whenever possible and ensure the indication is clearly documented on all medication orders.
- Where possible, consider the use of standardised naming conventions/order sentences in the eMeds system with the inclusion of the brand/trade name, strength and indication(s) to differentiate between misoprostol formulations, **or** the use of PowerPlans for specific indications to reduce prescribing selection errors.
- Consider implementing additional safety features available within eMM systems such as:
 - The use of prescribing and/or administration alerts to notify clinicians of the availability of different strengths of misoprostol, associated indications and risk of selection errors.
 - Co-signature functionality to enhance safety during administration.

Storage, distribution and dispensing

- Consider strategies as outlined in [Safety Information 006/24](#) to reduce medication errors including:
 - Physically separating the different strengths of misoprostol in storage areas by using shelf dividers or positioning in separate drawers or shelves.
 - Use additional warning labels on shelving and medicine packaging to alert to the potential risk of selection error involving misoprostol (e.g., 'PLEASE CHECK CAREFULLY – medicine with a similar name or appearance, confirm strength and indication').
 - Ensure misoprostol tablets are stored in their **original packaging** until immediately prior to dispensing and administration, unless:
 - individually dispensed and labelled, **or**
 - where a quantity smaller than the original pack size is required (ensure the active ingredient and strength is clearly visible).
 - Utilise barcode scanning to conduct checks when restocking imprest areas and automated storage systems, and during the dispensing process in the Pharmacy Department.

Administration

- Ensure clinicians adhere to policy regarding safe and accurate medication administration, including the 5 Rights (right patient, right drug, right dose, right time and right route) as outlined in the NSW Health Policy Directive *Medication Handling* (PD2022_032).
- Consider implementing independent second person checks prior to the administration of misoprostol. These checks should include (but are not limited to) carefully reading the medication label to verify the name, strength, form and route of administration against the medication order, rather than relying on packaging or label recognition. Refer to Sections 6.6 to 6.8 of NSW Health Policy Directive *Medication Handling* (PD2022_032) for more information.
- Where available, utilise barcode scanning at the point of administration to minimise selection error.

Potential for selection errors and harm with misoprostol tablets in maternity services

N SN: 014/25

APPENDIX 1

Table 1: Comparison of available misoprostol tablet products.

	Misoprostol (ANGUSTA) 25 microgram tablets	Misoprostol (CYTOTEC) 200 microgram tablets
Active ingredient and strength	Misoprostol 25 microgram	Misoprostol 200 microgram
Indication	<ul style="list-style-type: none"> Induction of labour at full term gestations 	<ul style="list-style-type: none"> Induction of labour in the context of termination of pregnancy and fetal death in utero in the second and third trimester Medical management of retained products of conception following miscarriage. Cervical preparation for surgical management of miscarriage or termination. Termination of intra-uterine pregnancy up to 63 days gestation, with mifepristone Maintenance treatment for the management of postpartum haemorrhage
NSW Medicines formulary restriction*	For the induction of labour in full term patients with an unfavourable cervix in accordance with a DTC approved protocol	For use as per registered indications OR off label use in accordance with a DTC approved protocol
Route of administration	Oral	Oral, sublingual, per vagina (PV)
Pack size	Pack of 8 tablets in foil blister	Pack of 120 tablets Strip of 10 tablets per foil blister
Associated clinical guidance documents	NSW Health Policy Directive <i>Induction of Labour</i> (PD2025_019)	NSW Health Guideline <i>Postpartum Haemorrhage</i> (GL2025_005) Refer to local DTC approved policies for other clinical indications
Presentation (images from MIMs)	White oval shaped tablet, featuring a score mark on one side 	White hexagonal shaped tablet, featuring a score mark on both sides 
Product images Carton artwork and foil strip		

*Current at time of publication.