Standard Operating Procedure (SOP)

Department:	Maternity/ Families & Therapies
SOP Ref No:	*Local SOP's - ABUHB/F&T/1335*
SOP Title:	**Induction of Labour with Misoprostol**

	NAME	TITLE	SIGNATURE	DATE
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Approved by:	**Extraordinary Induction of Labour Meeting**	**Extraordinary Induction of Labour Meeting**		**17/04 /2026**
	Clinical Effectiveness Forum (CEF)	**Clinical Effectiveness Forum (CEF)**		**27/04 /2026**
Issued to:	**ABUHB Maternity Services**			

Effective Date:	**20/04/2026**
Review Date:	**20/04/2029**

Change / Amendment History

Version No	Effective Date	Brief Summary of Changes	Author
Version 1	07/05/2026	• New document.	Hannah McLoughlin

1 Introduction

In response to the national circular issued by the Chief Pharmaceutical Officer on 8 April 2026, this Standard Operating Procedure (SOP) has been developed to support the safe implementation of changes arising from interruptions in the supply of Prostin® E2 (dinoprostone).

This SOP provides guidance to support safe medication management for the use of Angusta® 25 microgram (mcg) tablets for induction of labour, in response to the unavailability of the aforementioned medication.

This SOP should be read in conjunction with the local Induction of Labour Guideline (Aneurin Bevan University Health Board, 2026) and the Manufacturer's Instructions for Use for Angusta® 25 microgram tablets.

If you have difficulty understanding any part of this guideline- including due to learning, sensory, or communication needs- please speak with your Line Manager or contact the authors of this guideline for support or clarification.

Staff must take a proactive approach to identifying and meeting the accessibility and communication needs of people with disabilities and/or language barriers, including offering information in alternative formats, arranging interpretation or communication support as required, and not relying solely on individuals to request adjustments.

Aneurin Bevan University Health Board recognises that not all people having babies within Aneurin Bevan University Health Board identify as women.

2 Scope

This SOP applies to the use of Angusta® 25 mcg tablets for the induction of labour only.

Contraindications, cautions, and clinical considerations are detailed in Section 5 (Procedure).

3 Roles & Responsibilities

This SOP is intended for use by obstetric doctors and midwives undertaking induction of labour and is designed to support practitioners with sufficient training, competence, and experience to safely manage the procedure and any associated complications.

4 Procedure

Pre-induction of labour (IOL) assessment should proceed in accordance with the local Induction of Labour guideline (Aneurin Bevan University Health Board, 2025).

Please refer to Appendix 1 for the Induction of Labour with Angusta® flowchart.

Indications

Angusta® may be considered as a pharmacological method of induction of labour for women with prolonged rupture of membranes (PROM) or premature prolonged rupture of membranes (PPROM).

Regime and review

The standard regimen involves oral administration of 25 micrograms (mcg) every two hours, up to a maximum of eight doses (maximum total dose 200 mcg in 24 hours). This represents one complete cycle of treatment.

The decision to proceed with induction of labour with Angusta® should be Consultant-led.

Monitoring

Routine CTG monitoring is not required prior to each dose; however, a CTG must be performed before commencing induction of labour (IOL) and/or a cycle of Angusta®.

CTG monitoring should be performed 6-hourly during induction of labour with Angusta®. Further CTG assessment should be completed following the onset of regular uterine contractions or at any time if clinical concerns arise.

Vaginal Examination

Vaginal examinations should be performed as clinically indicated, such as with the onset of regular uterine contractions.

Warnings and Precautions for Use

The following cautions must be considered when prescribing or administering Angusta® for induction of labour. These are intended to support safe clinical practice and do not replace individualised clinical judgement or the need for senior obstetric review where indicated.

- Angusta® may cause excessive uterine activity; do not administer further doses if contractions become prolonged or excessive, or if there are concerns regarding maternal or fetal wellbeing. Manage in line with local guidance and escalate as required.
- Ensure fetal and maternal wellbeing prior to use.
- Use with caution where membranes have been ruptured for more than 48 hours, due to limited supporting evidence.
- Oxytocin must not be administered concurrently. A **minimum 4-hour interval** is required after the final dose before commencing oxytocin.
- Limited evidence exists for use in multiple pregnancy, grand multiparity, gestation under 37 weeks, or where the Bishop's score is greater than 7; senior obstetric review is recommended.
- Dose reduction or extended dosing intervals may be required in women with renal or hepatic impairment. Please refer to section 5.2 of the manufacturer's instructions for further information.
- Use with caution in the event of the following conditions-
    - Cardiovascular disease,
    - Cerebrovascular disease,
    - Conditions which predispose to diarrhoea, such as inflammatory bowel disease.

Full details of warnings, precautions, and additional safety information are provided in the manufacturer's instructions and should be consulted alongside this SOP.

Contraindications

Angusta® must not be used in the following circumstances:

- Known hypersensitivity or allergy to the active substance or any excipients contained within the formulation.
- Established labour.
- Suspected or confirmed fetal compromise prior to induction, including (but not limited to):
    - Abnormal fetal heart rate monitoring,
    - Meconium-stained liquor.
- Concomitant use of oxytocic agents or other pharmacological methods of labour induction.
- Known or suspected uterine scarring resulting from previous uterine or cervical surgery, including previous caesarean section or myomectomy.
- Structural uterine abnormalities that contraindicate vaginal birth (e.g., bicornuate uterus).
- Placenta praevia, or unexplained vaginal bleeding after 24 weeks' gestation in the current pregnancy.
- Fetal malpresentation where vaginal delivery is contraindicated.
- Severe renal impairment, defined as an estimated glomerular filtration rate (eGFR) less than 15 ml/min/1.73 m².

Use of this medication is contraindicated in the above circumstances and should not be initiated. Any uncertainty regarding eligibility must be escalated to the Consultant Obstetrician prior to prescribing or administration.

Undesirable effects

A table detailing undesirable effects associated with oral misoprostol use for induction of labour is provided in *Appendix 2*.

Breastfeeding

Misoprostol has been detected in human milk following oral administration of Misoprostol in tablet form.

Because of the extremely low levels of Misoprostol in breastmilk, amounts ingested by the infant are trivial and would not be expected to cause any adverse effects in breastfed infants. No special precautions are required (Drugs and Lactate Database, 2022).

Storage

Angusta® can be stored at room temperature in the original package in order to protect from moisture. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Reporting

Reporting of suspected adverse reactions after authorisation of the medicinal product should be via the Yellow Card Scheme.

5 References

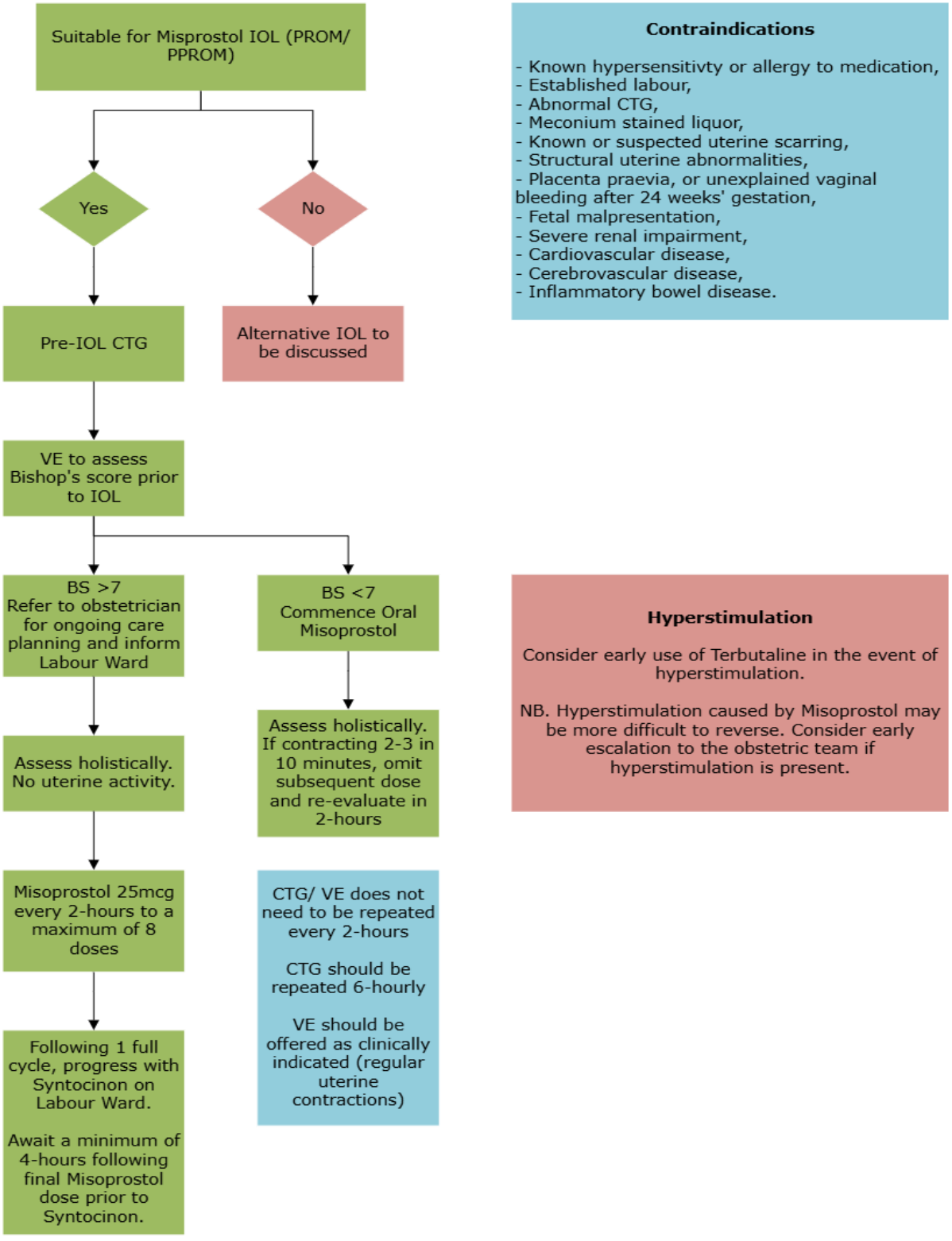
Aneurin Bevan University Hospital (2025). *Induction of Labour guideline* [Online]. Available at: https://wisdom.nhs.wales/health-board-guidelines/aneurin-bevan-file/induction-of-labour-iol-guideline/ (Accessed 20/04/2026)

Drugs and Lactate Database (LactMed®) (2022). *Misoprostol* [Online]. Available at: https://www.ncbi.nlm.nih.gov/books/NBK501436/ (Accessed 24/04/2026).

Emc (2025). *Augusta 25 microgram tablets* [Online]. Available at: https://www.medicines.org.uk/emc/product/12147/smpc (Accessed 20/04/2026).

6 Appendix

Appendix 1- Induction of Labour with Misoprostol



Appendix 2- Undesirable effects (emc, 2025)

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Not known (cannot be estimated from the available data) [1)]
Nervous system disorders				Dizziness Convulsion neonatal*
Respiratory, thoracic and mediastinal disorders				Neonatal asphyxia* Cyanosis neonatal*
Gastrointestinal disorders	*With 50 µg, 4-hourly:* Nausea[2)] Vomiting[3)]	Diarrhoea *With 25 µg, 2-hourly:* Nausea[2)] Vomiting[3)]		
Skin and subcutaneous tissue disorders				Rash pruritic
Pregnancy, puerperium and perinatal conditions	Meconium stain *With 25 µg, 2-hourly:* Postpartum haemorrhage[5)]	Uterine hyperstimulation[4)] *With 50 µg, 4-hourly:* Postpartum haemorrhage[5)]		Foetal acidosis* Premature separation of placenta Uterine rupture
General disorders and administration site conditions		Chills Pyrexia		
Investigations		*With 50 µg, 4-hourly:* Apgar score low*[6)] Foetal heart rate abnormal*[7)]	*With 25 µg, 2-hourly:* Apgar score low*[6)] Foetal heart rate abnormal*[7)]	

1) ADRs which were reported from the compassionate use programme including birth hospitals in Denmark, Norway and Finland, where approximately 29,000 women have been exposed to Angusta for induction of labour.

2) Nausea was common with 25 µg every 2 hours and very common with 50 µg every 4 hours.

3) Vomiting was common with 25 µg every 2 hours and very common with 50 µg every 4 hours.

4) Uterine hyperstimulation was reported both with and without foetal heart rate changes.

5) Postpartum haemorrhage was very common with 25 µg every 2 hours and common with 50 µg every 4 hours.

6) Apgar score low was uncommon with 25 µg every 2 hours and common with 50 µg every 4 hours.

7) Foetal heart rate abnormal was reported in connection with uterine hyperstimulation.