
Swansea Bay University Health Board

Induction of Labour Using Oral Misoprostol (Angusta) SOP

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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.

NICE NG207 provides guidance on circumstances for induction, assessment, monitoring, and methods used in UK practice and recommends the use of oral misoprostol as a pharmacological method for induction of labour

Recent evidence shows:

- Angusta® is at least as safe and effective as dinoprostone, with potential for lower caesarean birth rates.
- Angusta® is effective, safe and allows dose titration; it also has a favourable 2-hour half-life.
- Angusta® is well-tolerated and preferred by women compared to vaginal routes.
- Safety considerations include monitoring for tachysystole and avoiding use in women with previous caesarean section due to uterine rupture risk.

Several international guidelines (SOGC, RCOG SIP 68) now consider Angusta® a viable induction method, especially with low-dose commercial preparations

Angusta® (misoprostol) is licensed for induction of labour, Cytotec is not licensed for induction of labour.

This SOP should be read in conjunction with the local Swansea Bay UHB Induction of Labour policy.

2. PURPOSE

To provide a standardised, evidence-based protocol for the preparation, administration, and monitoring of Angusta® for induction of labour within Swansea Bay University Health Board, including inpatient and outpatient pathways.

3. SCOPE

This guideline applies to:

- Obstetricians
- Midwives
- Obstetric Anaesthetists
- Pharmacists
- Maternity Support Workers

It applies to women undergoing induction of labour at ≥ 37 weeks' gestation.

4. DEFINITIONS

Angusta® Low-dose oral misoprostol: 25 micrograms administered orally every 2 hours or 50 micrograms orally every 4 hours .

Tachysystole: ≥ 5 contractions in 10 minutes averaged over 30 minutes.

Hyperstimulation: Tachysystole associated with fetal heart rate abnormalities.

5. RESPONSIBILITIES

- Prescribing clinician: Assess suitability, obtain consent, prescribe correctly.
- Midwife: Administer medication, monitor maternal and fetal wellbeing.
- Pharmacist: Provide governance oversight for preparation process.
- Consultant Obstetrician: Available for escalation and complex cases.

6. INDICATIONS

Angusta® may be used for induction of labour in:

- Post-dates pregnancy (≥ 41 weeks)
- Maternal request (≥ 39 weeks following counselling and shared decision-making)
- Macrosomia $> 97^{\text{th}}$ centile without additional risk factors

- Term pre-labour rupture of membranes (PROM) (Misoprostol should be first line management for women with (P)PROM)
- Other obstetric and fetal indications where prostaglandin induction is appropriate
- Bishop score ≤ 6
- Maternal choice

7. CONTRAINDICATIONS

Angusta® must NOT be used in:

- Any uterine scar (including previous caesarean section, myomectomy, or other uterine surgery)
- Placenta praevia or unexplained vaginal bleeding
- Non-cephalic presentation
- Multiple pregnancy
- Known fetal compromise requiring urgent delivery
- Hypersensitivity to prostaglandins
- Suspected obstructed labour
- Established labour

Use with caution in:

- Cardiovascular disease
- Before 37 weeks
- Chorioamnionitis
- Cerebrovascular disease
- Conditions which predispose to diarrhoea (such as inflammatory bowel disease)
- Renal failure (eGFR <15)

8. DOSING AND PREPARATION

8.1 Standard Regimen

- Dose: 25 micrograms orally every 2 hours or 50 micrograms orally every 4 hours. **To reduce delays in medication administration SBU will administer 50mcg every 4 hours.**
- Maximum: 200 micrograms in 24 hours (4 doses) - one complete cycle
- Further cycles must be discussed with the consultant or senior obstetrician

There may be a synergistic/additive effect of misoprostol and oxytocin. Plasma concentrations of misoprostol acid are negligible after 5 half-lives (3.75 hours).

It is therefore recommended to wait 4 hours after the last dose of Misoprostol before administration of oxytocin.

8.3 Administration

- Take orally followed by some water
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9. SIDE EFFECTS

- Chills
 - Diarrhoea
 - Dizziness
 - Fever
 - Flatulence
 - Gastrointestinal upset
 - Nausea
 - Vomiting
 - Headaches
 - Skin reaction
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10. PROCEDURE FOR IOL

- Review plan by obstetrician and ensure woman is suitable for IOL using Angusta® oral misoprostol.
 - Ensure medication is prescribed
 - Baseline CTG prior to first dose for 30 minutes
 - Explain the method, evidence base, side effects and potential complications, alternative induction of labour methods available and alternative methods of birth
 - Perform baseline vaginal examination - if Bishop Score >6 contact labour ward to inform the woman is suitable for Artificial Rupture of Membranes and to liaise transfer when labour ward acuity allows
 - Administer Angusta® low dose oral Misoprostol 50mcg to be repeated 4 hourly (maximum of 4 doses 200mcg total dose).
 - Review the clinical picture prior to each further dose to include an assessment of fetal and maternal wellbeing, uterine activity, side effects experienced and the women's experience and wishes.
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11. INPATIENT MONITORING

- Baseline CTG prior to first dose
- CTG is not required after each dose
- Further monitoring should be performed following the onset of regular contractions or if concerns arise with vaginal loss, a change to fetal movements
- Monitor uterine activity and maternal observations.

- Withhold further doses if:
 - Labour is established
 - The patient is experiencing regular painful contractions
 - Tachysystole occurs
 - There is significant vaginal bleeding
 - Abnormal CTG
 - The woman experiences severe nausea and vomiting

12. MANAGEMENT OF HYPERSTIMULATION

If tachysystole with abnormal fetal heart rate:

1. Stop misoprostol.
2. Left lateral positioning.
3. Consider tocolysis (e.g., terbutaline) per emergency protocol.
4. Senior obstetric review.
5. Continuous CTG

Hyperstimulation can be treated with tocolysis however hyperstimulation caused by misoprostol may be more difficult to reverse

13. CONSENT

Women must be counselled regarding:

- Benefits and alternatives (mechanical methods, oxytocin if appropriate)
- Risk of uterine tachysystole
- Risk of failed induction
- Potential need for emergency caesarean section

Consent must be documented.

14. UNSUCCESSFUL INDUCTION

If no regular contractions following one full cycle of Angusta® (200mcg) perform vaginal examination. Discuss the findings with the woman, if Bishop Score <6 offer the woman the following:

- Repeat cycle of induction of labour with the same method or an alternative method
- A break in the induction process
- Cat 3 Caesarean section.

15. AUDIT AND GOVERNANCE

Annual audit should include:

- Mode of birth
- Time to active labour
- Hyperstimulation rates
- Neonatal outcomes
- Readmission rates (outpatient pathway)

Incidents must be reported via Datix in accordance with Health Board policy.

15. REFERENCES

1. World Health Organization. *WHO Recommendations for Induction of Labour*. Geneva: WHO; 2011.
2. Alfrevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD001338. DOI: 10.1002/14651858.CD001338.pub3.
3. UK Summary of Product Characteristics. Angusta 25 microgram tablets. Electronic Medicines Compendium ([Angusta 25 microgram tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) | 12147](#))