National Patient Safety Alert

NHS England

Department of Health & Social Care

Shortage of dinoprostone 3mg vaginal tablets and 1mg/2.5ml, 2mg/2.5ml vaginal gel

Date of issue:	8-Apr-26	**Reference no:**	NatPSA/2026/003/DHSC

This alert is for action by: All organisations involved in prescribing, dispensing and administering dinoprostone (Prostin® E2)3mg vaginal tablets (pessary) and dinoprostone (Prostin® E2) 1mg/2.5ml and 2mg/2.5ml vaginal gel.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in gynaecology, obstetrics, maternity and pharmacy services in secondary care settings.

Explanation of identified safety issue:

Pfizer has advised that quality issues affecting the raw materials used in manufacturing have resulted in supply interruptions for their Prostin® E2 (dinoprostone) range, as follows:

- Prostin® E2 3 mg vaginal tablets (pessary): unavailable until October 2026
- Prostin® E2 1 mg/2.5 ml gel: unavailable from 4 May to 3 August 2026
- Prostin® E2 2 mg/2.5 ml gel: unavailable from 13 April to 7 September 2026.

Other uterotonic products remain available and can support additional demand in varying amounts:

- Propess® (dinoprostone) 10 mg vaginal delivery system can support full demand
- Angusta® (misoprostol) 25 micrograms tablets can support partial demand
- Oxytocin 5 units/1 ml and 10 units/1 ml ampoules can support partial demand

Limited quantities of unlicensed dinoprostone vaginal tablets and gels can be sourced, but lead times may vary.

For the most up-to-date information on expected re-supply dates and unlicensed import options, please consult the dinoprostone page on the Medicines Supply Tool.

Actions required

Actions to be completed by 20/04/2026 and to remain in place only until the supply issues have resolved:

1. Hospital Procurement Teams should review current stock of all Prostin® E2 presentations and coordinate urgent ordering of unlicensed imports, where available.
2. Remaining stock of Prostin® E2 vaginal gel should be reserved for patients where other options are contraindicated or unsuitable, for example patients with ruptured membranes (see Note A).
3. Clinicians should limit repeat prostaglandin inductions if labour does not start. Consider mechanical methods if pharmacological induction is unsuitable or unsuccessful (see Note A).
4. Hospital Trusts and clinicians should update local guidelines or patient group directions (PGDs) to reflect any changes required during the shortage.
5. All healthcare staff impacted by this shortage should be appropriately trained in any new procedures.
6. NHS Trusts should ensure required storage conditions and handling procedures are in place when practice changes are implemented (see Note B).

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Note A: Clinical Guidance
Specialists in maternity and obstetrics have developed the table below on alternative options during the current Prostin® E2 shortage, including recommendations on prioritising any remaining stock.

National Institute for Health and Care Excellence (NICE) Guidance:

- **NG207 – Inducing Labour:** For women with a Bishop score* of ≤6, offer induction of labour with dinoprostone as a vaginal tablet, vaginal gel, or controlled-release vaginal delivery system, or with low-dose (25 microgram) oral misoprostol tablets.

Recommended Alternatives During Prostin® E2 Shortage:

Indication	Current Recommended Treatment	Alternatives / Advised Switch During Shortage
Term, low-risk induction of labour	Propess® (dinoprostone) vaginal delivery system or Prostin® E2 (dinoprostone) vaginal gel or tablet	Switch to Propess® or consider misoprostol or mechanical methods (balloon catheter) as first-line options
Low-risk induction of labour that has failed after 1–2 treatments	Propess® or Prostin® E2	Switch to mechanical methods (balloon catheter) or misoprostol
Premature rupture of membranes (PROM)	Prostin® E2 or oxytocin	Reserve any remaining Prostin®E2 stock specifically for patients with PROM; if Prostin®E2 is unavailable use IV oxytocin
Induction of labour before 37 weeks	Propess® or Prostin® E2	Switch to Propess®, or consider misoprostol or mechanical methods (balloon catheter)

*Bishop score: a clinical scoring system to assess cervical readiness for induction of labour.

In cases of intrauterine fetal death where dinoprostone is used in protocols in association with misoprostol, we would recommend the sole use of misoprostol in this period.

Note B: Storage considerations
Please note that Propess® (dinoprostone) vaginal delivery system should be stored in a freezer at -10 to -25°C in its original container. No thawing is required prior to use.

References:

BNF Dinoprostone
SmPC Dinoprostone
BNF Misoprostol
SmPC (Augusta) Misoprostol
BNF IV Oxytocin
SmPC IV Oxytocin

Inducing labour. NICE guideline. Reference number:NG207 Published: 04 November 2021
NHS England » National Patient Safety Alert – risk of oxytocin overdose during labour and childbirth

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service Medicine Advice; Medicine Shortage Response Group; NHS England; national clinical experts in obstetrics and maternity; Medicines and Healthcare products Regulatory Agency, and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers
This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.