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Pfizer Limited
Walton Oaks, Dorking Road,
Tadworth, Surrey,
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May 2026

Pfizer Limited Prostin E2 3 mg Vaginal Tablets (dinoprostone);
PL 00057/1516

Interim supply from AfME region

Dear Healthcare Professional,

Summary:

Due to a temporary disruption in the supply of Prostin E2 3 mg Vaginal Tablets (dinoprostone), Pfizer Limited has, in order to maintain continuity of supply, obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to release UK stock from batches originally manufactured for the Africa & Middle East (AfME) market.

The affected packs (batch numbers 240406A and 240407B) are expected to be available on the UK market from May 2026 through July 2026.

Active ingredient: Dinoprostone
Legal Category: POM: Prescription only medicine
Manufacturer: Pfizer Limited

Please note the following:

- Please **discard** the PIL that is included in the box and refer to the attached UK PIL
- There are differences in wording in the Patient Information Leaflet (PIL), label and carton as these are multilingual (Arabic/EN)
- Please note that the Patient Information Leaflet included in the pack includes information for both **oral and vaginal administration**, however this product is for **vaginal administration only**. Healthcare professionals should therefore discard the PIL included in the pack and instead refer to and provide patients with the attached UK PIL. Prescribing and use should be in accordance with the UK SPC.
- There is a difference in pack size: The AfME stock contains 4 x tablets per pack, whereas the UK stock contains 8 x tablets per pack
- These batches have been approved for supply to the UK market and should be used in accordance with the UK SPC and UK Patient Information Leaflet
- Please ensure the UK SPC and PIL are followed.

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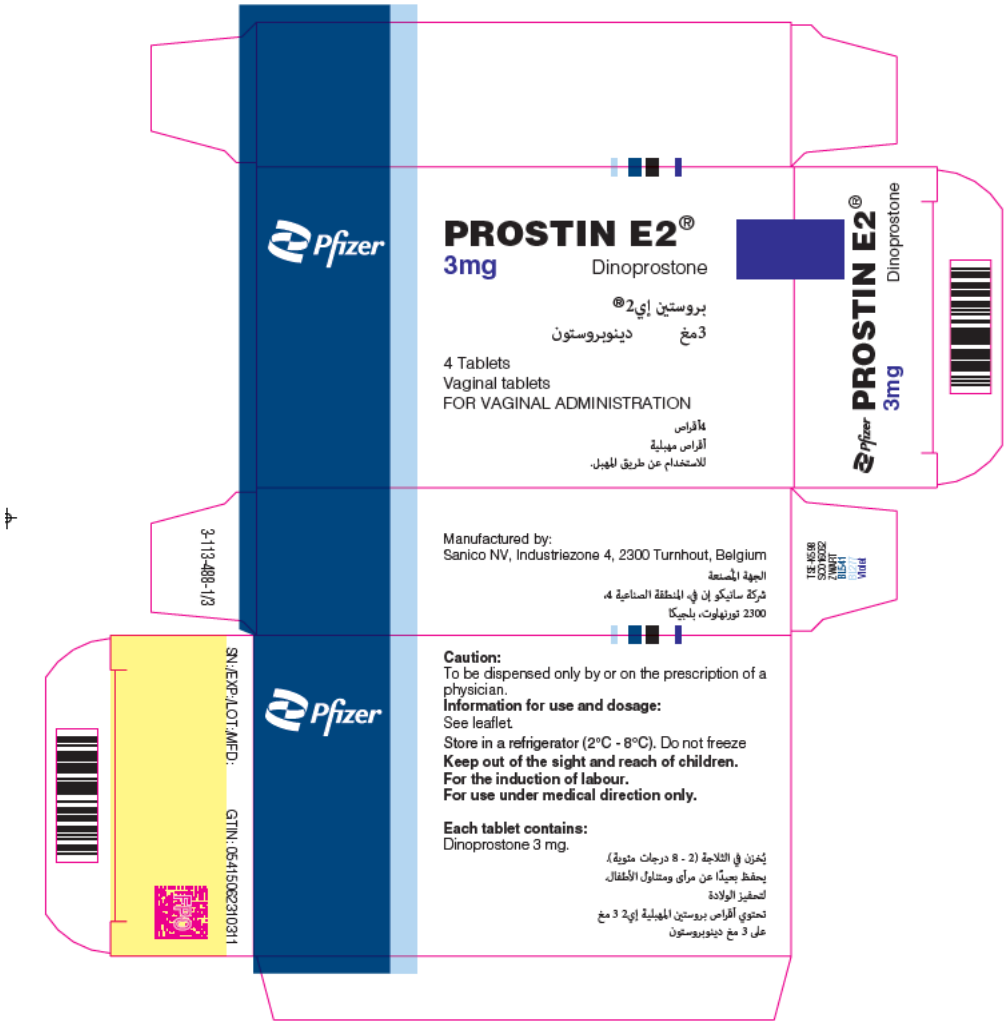
Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients and caregivers.

Prostin E2 is only available to hospitals and clinics with specialised obstetric units and should only be used where 24-hour resident medical cover is provided.

Please refer to the PIL/SPC for further details.

Product images are below.



Call for reporting

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Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point
For any questions, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616 161 or https://www.pfizermedicalinformation.co.uk.

Yours faithfully,

DocuSigned by:
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Monica Nijher
Pfizer UK Country Medical Director
Pfizer UK