Medicines & Healthcare products Regulatory Agency

M E D I C I N E S R E C A L L

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 19 March 2024 EL (24)A/09 Our Ref: MDR 333-02/24

Dear Healthcare Professional,

Besins Healthcare (UK) Ltd

Oestrogel Pump-Pack 750 micrograms/actuation Gel (estradiol) PL 28397/0002

SNOMED Code 3414911000001105

Batch No	Expiry Date	Pack Size	First Distributed
74800	31/07/2026	1	06/11/2023
74830	31/08/2026	1	08/11/2023

Active Pharmaceutical Ingredient: estradiol

Brief description of the problem
Besins Healthcare (UK) Ltd has informed the MHRA that a defective pump system was detected in two batches of Oestrogel Pump-Pack 750 micrograms/actuation Gel. The product pumps are subject to mechanical faults which result in the failure to dispense the product and in some cases, the detachment of the pump from the container. It is estimated that 11% of units across the two batches could be affected by the defect.

Where the pump is functioning, there is no impact on the quality or safety of the Gel and therefore this is not a patient level recall.

Advice for healthcare professionals
Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process. Follow your company's returns procedure through your wholesaler to arrange a credit note or contact Besins (see Further Information below for contact details).

If a patient presents with a defective pump from these batches a replacement product will be required. The Department of Health and Social Care (DHSC) has confirmed that, as this is a prescription only medicine, a new prescription will be required for the dispensing of a replacement product.

The majority of patients who have received this product will be entitled to free prescriptions or have arrangements in place for a HRT pre-payment certificate and therefore a new prescription will not incur any additional costs. Where patients pay for NHS prescriptions, a charge for the new prescription will apply; patients may contact the Defective Medicines Reporting Centre if further information is required.

Besins Healthcare (UK) Ltd has confirmed that all other batches are unaffected and that there is no impact on supply.

Advice for patients
Patients who experience issues with a pump from the batches specified in the table should return the defective pumps to their pharmacy. As this is a prescription only medicine, a new prescription will be required for the dispensing of a replacement product. Patients with a HRT pre-payment certificate will not incur any additional costs. Where patients pay for NHS prescriptions, a charge for the new prescription

will apply; patients may contact the Defective Medicines Reporting Centre if further information is required.

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. Where the pump is functioning correctly, patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Patients who experience adverse reactions, defective medicines or have any questions about the medication, should seek medical attention and report their symptoms to pharmacovigilance@besins-healthcare.com . Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
For medical information enquiries please contact the Besins Healthcare UK Ltd Medical Information via email besins@eu.propharmagroup.com or by calling +44 (0)1748 828 789.

For stock control enquiries please contact Besins Healthcare UK Ltd Supply Chain via email supplychain-bhuk@besins-healthcare.com.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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