March, 2024

Direct Healthcare Professional Communication

Oestrogel (estradiol) Pump-Pack 750 micrograms/actuation Gel Recall

Dear Healthcare Professional,

Besins Healthcare in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

A defective pump system was detected in two batches of Oestrogel (estradiol) Pump-Pack 750 mcg/actuation Gel. The pumps are subject to mechanical faults which result in the failure to dispense product and in some cases, the detachment of the pump from the container. A Class 3 Recall to Wholesale/Pharmacy level for the affected batches has been agreed.

Besins Healthcare has also received some complaints related to the reintroduction of the cylindrical Oestrogel bottles, and concerns regarding the efficacy of the gel, or sub-optimal dosages dispensed.

Recall of batches due to defective pumps

The affected batch numbers are:

- 74800 (expiry date 31/07/26)
- 74830 (expiry date 31/08/26)

These batches have been recalled; all other batches are unaffected. There is no impact on supply.

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, particularly as continuity of treatment is important for HRT products.
  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 and/or have arrangements in place for an 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.

Reintroduction of cylindrical Oestrogel bottles:

Besins Healthcare continues to conduct further investigations of reported product quality complaints, patient returned samples, market samples and samples held at manufacturing sites. The analyses performed did not identify a root cause that confirms concerns regarding the efficacy of the gel, or sub-optimal dosages dispensed from the Oestrogel bottles in question. The testing methods used adhere to the required quality standards.

To ensure a continuous supply, we have prioritised providing Oestrogel in the cylindrical bottle (white lid), and at present the supply is limited to the cylindrical bottle only. Both conical and cylindrical bottles contain the same gel manufactured with the same ingredients from the same suppliers. The gel formulation has not been changed.

We are committed to our ongoing investigations and will continue to collect samples for further examination. Once we have received the final outcomes from the investigation, we will provide updates to those who have lodged complaints.

Call for reporting:

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card scheme.

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 9 am and 5 pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name

If your patient has experienced a recurrence of symptoms, this should be reported via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard in the United Kingdom or to www.hpra.ie in the Republic of Ireland as well as to pharmacovigilance@besins-healthcare.com.

Company contact point:

If you would like to submit a complaint that a pump-pack is not functioning correctly, please contact ukquality@besins-healthcare.com. This action will facilitate a comprehensive investigation into the matter.

If you have further questions, please contact besins@eu.propharmagroup.com.

Thank you for your understanding.

DocuSigned by:
Sangeeta Sharma
Signer Name: Sangeeta Sharma
Signing Reason: I approve this document
Signing Time: 19 mars 2024 | 5:58:32 PM CET
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