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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

5 September 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 3 DRUG ALERT 34 2023 – CLASS 3 MEDICINES RECALL – ACTION WITHIN 5 DAYS – THERAMEX HQ UK LTD - EVOREL SEQUI

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 05 September 2023

EL (23)A/34

Our Ref: MDR 240-08/23

Dear Healthcare Professional,

Theramex HQ UK Ltd

Evorel Sequi

PL 49105/0010

SNOMED Code: 3217311000001104

Batch No	Expiry Date	Pack Size	First Distributed
6029403	July 2024	8 patches	13th June 2023

Active Pharmaceutical Ingredient: each pack of Evorel Sequi contains eight patches; four (4) Evorel 50 patches (containing estradiol only) and four (4) Evorel Conti patches (containing estradiol and norethisterone).

Brief description of the problem

Theramex has informed the MHRA that some cartons of Evorel Sequi contain the incorrect combination of patches. An error at the packaging site means that a limited number of packs have the incorrect combination of Evorel 50 and Evorel Conti patches. Only the batch listed in this notification is affected. The remainder of the batch is being recalled as a precautionary measure. The batch is comprised of 150,132 packs. So far 24 packs have been confirmed to contain the incorrect combination and the investigation has concluded that the issue is limited to a small number of packs only.

Advice for healthcare professionals

Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

If a patient presents with the incorrect patches, they should be dispensed a correct pack from another batch. Theramex has confirmed that all other batches are unaffected and that there is no impact on supply.

For prescriptions written within the last 6 months, check the pack being returned by the patient and the dispensing record (Summary Care Record may be checked with the patient's consent). Following advice from the Department of Health and Social Care, this is considered a correction to the original prescription and a further prescription would not be necessary. Follow your company's returns procedure through your wholesaler to arrange a credit note or contact Theramex (see Further information below for contact details).

Advice for patients

Patients who may have received the impacted batch of Evorel Sequi should consider the following information:

- Check the contents of your pack to ensure that it contains four (4) Evorel 50 patches and four (4) Evorel Conti patches. The packaging is clearly labelled with the medication names.



Medicines & Healthcare products Regulatory Agency

- If you have received four (4) of each patch, please continue to take the medicine as prescribed by your healthcare professional. You do not need to take any action.
- If you do not have 4 of each patch, please contact your pharmacist. If the prescription was written within the past 6 months, the pharmacist will arrange for the dispensing of a correct pack from another batch. Alternatively, contact your GP directly as a new prescription may be required.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact the Theramex Medical Information Department on 033 3009 6795 or via email: medinfo.uk@theramex.com

For pharmacy stock control enquiries please contact Alliance Customer Services Team on 020 3962 5555.

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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