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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

12 September 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 41 2024 – 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: 12 September 2024

EL (24)A/41

Our Ref: DMRC-31752921

Dear Healthcare Professional,

Theramex HQ UK Ltd

Evorel Sequi

PL 49105/0010

SNOMED Code 3217311000001104

Batch No	Expiry Date	Pack Size	First Distributed
6137001	September 2025	8 patches	12 April 2024

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 112,728 packs. So far 19 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, a replacement pack will be required. Theramex has confirmed that all other batches are unaffected and that there is no impact on supply. 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.

Some patients who have received this product will be entitled to free prescriptions through existing exemptions, 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.



Medicines & Healthcare products Regulatory Agency

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.
- 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 for further advice and arrangement for dispensing of a replacement product.

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 via medinfo.uk@theramex.com or call 0333 009 6795.

For stock control enquiries please contact Alliance Customer Services Team on 0330 100 0448.

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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