

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

Dear Healthcare Professional

Galderma (U.K.) Limited

Epiduo 0.1% / 2.5% gel (45 g)

PL 10590/0057

SNOMED Code 17403011000001101

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|-----------|---------------------|
| 1324283 | 30-Nov-23 | 1 x 45g | 18-Mar-22 |
| 1324288 | 30-Nov-23 | 1 x 45g | 18-Mar-22 |
| 2324207 | 31-Jan-24 | 1 x 45g | 09-Jun-22 |
| 2324212 | 31-Mar-24 | 1 x 45g | 31-May-22 |
| 2324218 | 30-Apr-24 | 1 x 45g | 14-Jul-22 |
| 2324227 | 30-Apr-24 | 1 x 45g | 26-Jul-22 |
| 2324228 | 30-Apr-24 | 1 x 45g | 12-Sep-22 |
| 2324228A | 30-Apr-24 | 1 x 45g | 30-Sep-22 |
| 2324237 | 31-May-24 | 1 x 45g | 30-Nov-22 |
| 2324238 | 31-May-24 | 1 x 45g | not yet distributed |
| 2324239 | 30-Jun-24 | 1 x 45g | not yet distributed |
| 2324248 | 31-Aug-24 | 1 x 45g | not yet distributed |
| 2324249 | 30-Sep-24 | 1 x 45g | not yet distributed |
| 2324259 | 30-Sep-24 | 1 x 45g | not yet distributed |
| 2324265 | 30-Sep-24 | 1 x 45g | not yet distributed |

Active Pharmaceutical Ingredient: Adapalene 1 mg (0.1%); Benzoyl Peroxide 25 mg (2.5%)

Brief description of the issue

Galderma (U.K.) Limited has informed the MHRA that the Patient Information Leaflet (PIL) packaged in the above batches of Epiduo 0.1% / 2.5% gel contains outdated safety information regarding pregnancy.

Details of the discrepancies are listed in the table below.

Extract from PIL section 2 (“What you need to know before you use Epiduo”)

| | |
|--|---|
| <p>The <u>erroneous version</u> of the leaflet packed with these batches contains the following wording:</p> <p><u>Do not use Epiduo:</u></p> <ul style="list-style-type: none">- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6). <p><u>Pregnancy and breast-feeding</u> Epiduo should not be used during pregnancy</p> <p>If you fall pregnant while taking Epiduo, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.</p> <p>...</p> <p>Ask your doctor or pharmacist for advice before taking any medicine.</p> | <p>The <u>correct version</u> of the leaflet should include the following wording (missing/changed information highlighted <i>in italics</i>):</p> <p><u>Do not use Epiduo:</u></p> <ul style="list-style-type: none">- <i>If you are pregnant</i>- <i>If you are planning a pregnancy</i>- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6). <p><u>Pregnancy and breast-feeding</u> <i>DO NOT use Epiduo if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.</i></p> <p>If you fall pregnant while taking Epiduo, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.</p> <p>...</p> <p>Ask your doctor or pharmacist for advice before taking any medicine.</p> |
|--|---|

Advice for healthcare professionals

There is no risk to product quality as a result of this issue. Healthcare professionals are advised to exercise caution when dispensing the above batches of the product. Where possible, please provide an updated copy of the PIL to the patient and remind the patient to **read the leaflet in its entirety before using the medicine**. This is available via the link below:

[Epiduo 0.1%/2.5% Gel - Patient Information Leaflet \(PIL\) - \(emc\) \(medicines.org.uk\)](http://www.medicines.org.uk)

Where available, Galderma (U.K.) Limited will be providing the updated PIL with all future deliveries for the affected batches. Upon request, Galderma (U.K.) Limited will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information.

Advice for patients

If you are pregnant or planning a pregnancy you should be aware that the Patient Information Leaflet (PIL) in the above batches of Epiduo 0.1% / 2.5% gel does not contain the most up-to-date safety information. Specifically, you are reminded that you should not use this product when pregnant and furthermore you should not use the product when planning a pregnancy.

Please inform your doctor if you are pregnant or planning a pregnancy.

Any suspected adverse reactions should be reported via the MHRA [Yellow Card scheme](#).

Further Information

For more information, medical information queries or replacement PIL enquiries, please contact: medinfo.uk@galderma.com

For stock control queries, please contact: sales.uk@galderma.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.



The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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19th December 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>