



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

### Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 19 December 2022

EL (22)A/52

Our Ref: MDR 031-12/22

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the MHRA that the Patient Information Leaflet (PIL) packaged in the above batches of Epiduo 0.1% / 2.5% gel contains outdated safety information regarding pregnancy.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 overleaf.



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"> <li>- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).</li> </ul> <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"> <li>- <i>If you are pregnant</i></li> <li>- <i>If you are planning a pregnancy</i></li> <li>- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).</li> </ul> <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>
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**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 \(PIL\) - \(emc\) \(medicines.org.uk\)](https://www.medicines.org.uk/emc/leaflets/2019/02/201902001)

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](mailto:medinfo.uk@galderma.com)

For stock control queries, please contact: [sales.uk@galderma.com](mailto:sales.uk@galderma.com)

Recipients of this Medicines Notification 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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