

GALDERMA

EST. 1981

MEDICINES NOTIFICATION CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 20th December 2022

Dear Healthcare Professional,

Galderma International Limited

Epiduo 0.1% / 2.5% gel (45 g)

MA 117/01202

Batch No	Expiry Date	Pack Size	First Distributed
2324218	30-Apr-24	1 x 45g	04-Oct 2022

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

Brief description of the issue

The Medicines & Healthcare products Regulatory Agency of the United Kingdom through its Defective Report Centre has issued a Class 4 Medicines Defect Information Notification on the 19th December 2022 (MHRA ref No. MDR 031-12/22) stating that the Patient Information Leaflet (PIL) packaged in the above batch of Epiduo 0.1% / 2.5% gel contains outdated safety information regarding pregnancy.

[Class 4 Medicines Defect Information: Galderma \(U.K.\) Limited, Epiduo 0.1% / 2.5% gel \(45 g\), EL \(22\)A/52 - GOV.UK \(www.gov.uk\)](#)

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"> - 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>
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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 \(PIL\) - \(emc\) \(medicines.org.uk\)](http://www.medicines.org.uk)

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 Medicines Authority portal: www.medicinesauthority.gov.mt/adrportal

Further Information

For more information, medical information queries or replacement PIL enquiries, please contact: pharmacovigilance@prohealth.com.mt

For stock control queries, please contact: info@prohealth.com.mt

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

Yours faithfully;

GALDERMA

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