



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 06 December 2022

EL (22)A/51

Our Ref: MDR 108-11/22

Dear Healthcare Professional,

Galderma (U.K.) Limited

Etrivex 500 micrograms/g Shampoo

PL 10590/0052

SNOMED Code 11771611000001109

Batch No	Expiry Date	Pack Size	First Distributed
0114252	07/2023	1 x 125ml	01/10/2020
0114277	07/2023	1 x 125ml	23/12/2020
0114291	04/2023	1 x 125ml	19/03/2021

Active Pharmaceutical Ingredient: Clobetasol propionate

Brief description of the problem

Galderma (U.K.) Limited has informed the MHRA that the patient information leaflet (PIL) packaged in specific batches of Etrivex Shampoo is missing the following safety information (in bold):

Section 2: What you need to know before you use Etrivex 500 micrograms/g shampoo

Warnings and precautions

Take special care with Etrivex 500 micrograms/g Shampoo

- When using Etrivex shampoo, it must only be used on the scalp, do not use it as a regular shampoo or on other areas of the body and do not use Etrivex shampoo as a shower gel, body wash or bath foam.
- When treating the scalp with Etrivex shampoo you must not cover the area being treated, for example: a shower cap must not be used as it may make the active substance pass through the skin and affect the other parts of the body.
- When using Etrivex shampoo, avoid contact with the face, eyelids, axillae (armpits), erosive skin (chapped skin) surface and genital regions. Rinse off immediately with water if any product runs from the scalp.
- If you get Etrivex shampoo in your eye(s), wash the affected eye thoroughly with water. If any irritation persists, please seek advice from your doctor.
- If you do not notice an improvement of your scalp psoriasis, please see your doctor.
- **Contact your doctor if you experience blurred vision or other visual disturbances.**



Section 4: Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Etrivex shampoo may cause the following side effects

Not known (frequency cannot be estimated from the available data)

- Blurred vision

Advice for healthcare professionals

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing specific batches of the product. Where possible, 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:

[Etrivex 500 micrograms/g Shampoo - Patient Information Leaflet \(PIL\)](#)

Galderma (U.K.) Limited has confirmed that all future batches will contain the correct PIL. 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

Patients should be aware that the Patient Information Leaflet (PIL) in the above batches of Etrivex 500 micrograms/g Shampoo does not contain the most up-to-date safety information on side effects.

If you experience blurred vision and visual disturbances, you should contact your doctor immediately. Any suspected adverse reactions should also 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.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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