



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 17 February 2022

EL (22)A/07

Our Ref: MDR 233-01/22

Dear Healthcare Professional,

Uni Health Distribution

Efudix 5% w/w cream

PL 45396/0088

Batch Number	Expiry Date	Pack Size	First Distributed
80193439/B	11/2025	2 x 20g	28/10/2021

Active Pharmaceutical Ingredient: Fluorouracil

Brief description of the problem

Uni Health Distribution is aware of a potential issue where the leaflet contained within Efudix 5% w/w cream (2 x 20g) pack, batch 80193439/B may be incorrect. The issue was identified due to a market complaint which noted that 'Trajenta 5mg tablets leaflet has been found in an Efudix 5% w/w cream.' Uni Health Distribution have checked the packs within their possession and have not identified this issue in other packs, however the batch is being recalled from pharmacies as a precautionary measure.

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.

Uni Health Distribution and impacted suppliers will be contacting the pharmacies directly who have been supplied the product. Healthcare professionals are urged to share an appropriate leaflet with the patient where possible. This product has been distributed in small volumes and based on the specific need for patients, this product is not being recalled from patients. The correct leaflet can be found here: [Link to Efudix 5% w/w Cream PIL](#)

Further Information

For more information, please contact or email Margaret Fairney (margaret@ennogen.com)

For medical information queries, please contact or email Margaret Fairney (margaret@ennogen.com)

For supply queries, please contact Davide Rinaldi (purchasing@ennogen.com)

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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