



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 18 January 2023

EL (23)A/02

Our Ref: MDR 056-01/23

Dear Healthcare Professional,

UCB Pharma Ltd.

Diocetyl 100 mg Capsules

PL 00039/0737

SNOMED Code 773111000001101

Batch No	Expiry Date	Pack Size	First Distributed
322983D	30 Jun 2023	1 x 100 capsules	16 Dec 2021

Active Pharmaceutical Ingredient: Docusate Sodium

Brief description of the problem

UCB Pharma Ltd is recalling the above batch of product as a precautionary measure due to the presence of a foreign capsule being found in a sealed pack. The Marketing Authorisation Holder's investigation concluded that this was the result of a product mix up during the manufacturing process.

The foreign capsule detected was a blue/green capsule marked with the text 'IM02', whereas Diocetyl 100 mg Capsules are opaque yellow and white soft gelatin capsules containing a clear, colorless liquid. The foreign capsule has been identified as loperamide 2mg capsules.

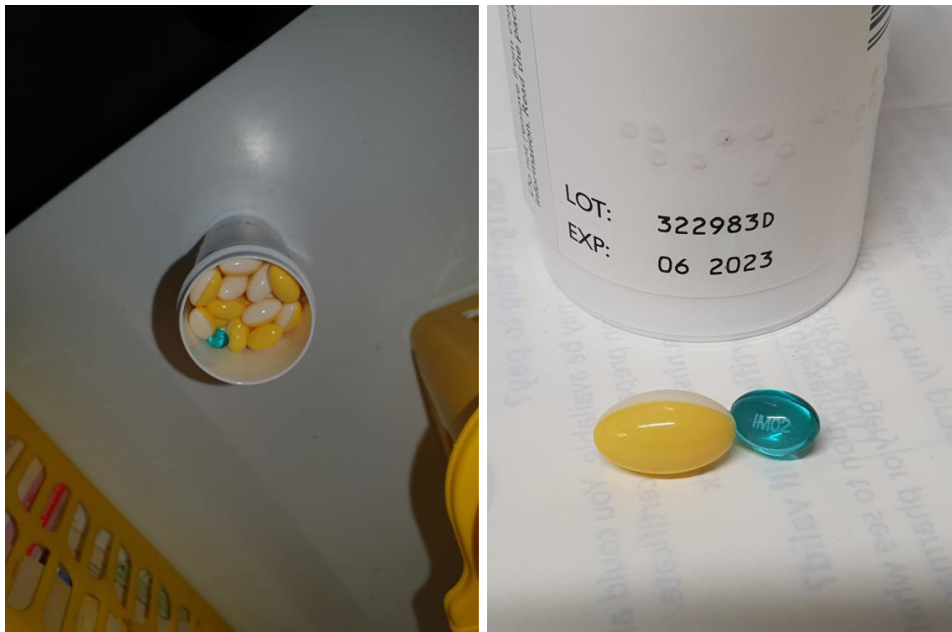


Image 1: Presence of foreign capsule in a sealed pack of Diocetyl 100mg Capsules (batch 322983D)

Image 2: Comparison of Diocetyl 100mg Capsules and the foreign capsule



Medicines & Healthcare products Regulatory Agency

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.

Advice for patients

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. However, if patients discover foreign capsule(s) with a different appearance in a sealed pack of Dioctyl 100mg Capsules, please return the pack to your pharmacy for a replacement. Do not consume the foreign capsule. Any suspected defective medicine should be reported via the [MHRA Yellow Card scheme](#).

Patients who experience adverse reactions or insufficient control of symptoms should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For more information, medical or supply enquiries, please contact UCB Pharma Ltd on (+44) 01753 777100 or 0800 279 3177 (freephone) or by email UCBCares.UK@ucb.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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