

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

UCB Pharma Ltd.

Dioctyl 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 Dioctyl 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.

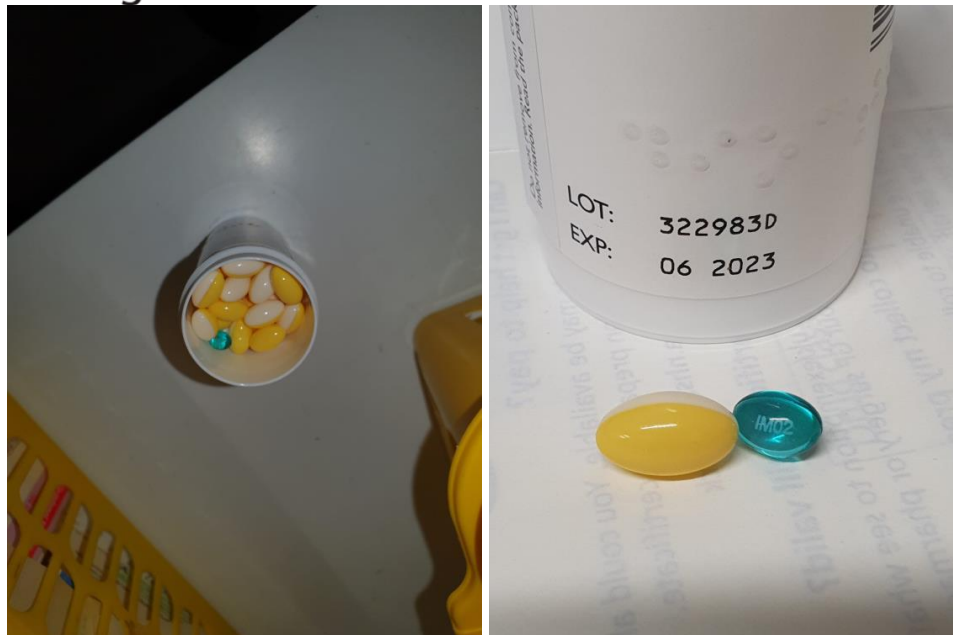


Image 1: Presence of foreign capsule in a sealed pack of Dioctyl 100mg Capsules (batch 322983D)

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

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. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

18th January 2023

Pharmaceutical website: <http://www.hscbusiness.hscni.net>