



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 11 April 2022

EL (22)A/17

Our Ref: MDR 209-03/22

Dear Healthcare Professional,

USV UK Limited

Olopatadine USV 1mg/mL eye drops, solution

PL 32870/0055

Batch Number	Expiry Date	Pack Size	First Distributed
35000201	07/2023	5 mL	14 July 2021
35000202	07/2023	5 mL	27 July 2021
35000203	07/2023	5 mL	5 August 2021
35000204	07/2023	5 mL	29 November 2021
35000206	07/2023	5 mL	23 July 2021

Active Pharmaceutical Ingredient: Olopatadine hydrochloride

Brief description of the problem

USV UK Limited are recalling the affected batches as a precautionary measure due to out of specification results for impurities during routine stability testing. The company's investigation is on-going.

Advice for healthcare professionals

Stop supplying the above batches 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.

Although the Marketing Authorisation Holder have not received any reports of adverse reactions related to the issue above, patients who experience adverse reactions should seek immediate 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 info@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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