



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 27 April 2022

EL (22)A/19

Our Ref: MDR 136-03/22

Dear Healthcare Professional,

Crescent Pharma Limited

Paroxetine 40mg Film Coated Tablets

PL 20416/0363

Batch Number	Expiry Date	Pack Size	First Distributed
06309	September 2023	30 tablets	19 Feb 2021

Active Pharmaceutical Ingredient: paroxetine

Brief description of the problem

Crescent Pharma Limited are recalling the above batch of product as a precautionary measure due to out of specification results for dissolution during routine stability testing.

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

- This is a precautionary Pharmacy and Wholesaler level recall, therefore no further action is required by patients.
- Patients should continue taking your medicines from this batch, as stopping paroxetine treatment abruptly is likely to cause harm.
- The Marketing Authorisation Holder have not received any reports of adverse reactions related to the issue above, however, patients who experience a change of their condition or symptoms, or any adverse reactions should seek medical attention. These should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For more information, medical or supply enquiries, please contact 01256 772730

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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