



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 days
Pharmacy/Wholesaler Level Recall

Date: 14 December 2023

EL (23)A/44

Our Ref: MDR 090-12/23

Dear Healthcare Professional,

Biocon Pharma UK Limited

Posaconazole Biocon 100mg Gastro-resistant Tablets

PL 50674/0011

SNOMED Code N/A

Batch Number	Expiry Date	Pack Size	First Distributed
BF22004504	Dec-2024	12 x 8	27 th April 2023

Active Pharmaceutical Ingredient: Posaconazole

Brief description of the problem

Biocon Pharma UK Limited are recalling a specific of batch Posaconazole 100mg Gastro-resistant Tablets due to an out of trend result for unspecified impurities during testing for stability. The batch is likely to be out of specification before the expiry date and therefore the batch is being recalled as 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.

Advice for patients

No further action is required by patients, these batches are being recalled at the pharmacy and wholesaler level as a precautionary measure. Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For product quality complaints and medical information enquiries contact PQCSMV@biocon.com. For reporting adverse events contact drugsafety.smv@biocon.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

Defective Medicines Report Centre

10 South Colonnade

Canary Wharf

London

E14 4PU

Telephone +44 (0)20 3080 6574 / DMRC@mhra.gov.uk