



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Pharmacy/Wholesaler Level Recall

Date: 23 October 2024

EL (24)A/50

Our Ref: DMRC-32910584

Dear Healthcare Professional,

Bristol Laboratories Ltd

Phenobarbital Bristol Labs 15mg Tablets

PL 17907/0175

SNOMED Code 21039211000001106

Batch No	Expiry Date	Pack Size	First Distributed
NU22001	10/2025	28's	21 Dec 2022

Active Pharmaceutical Ingredient: Phenobarbital

Brief description of the problem

Bristol Laboratories Ltd. are recalling one batch of Phenobarbital Bristol Labs 15mg Tablets as a precautionary measure due to the potential of contamination of small metallic particles within the tablets. Bristol Laboratories have received one single market complaint relating to a tablet which had been cut in half by the patient prior to administration, revealing the small metallic particle within the tablet core. There have been no other similar reports related to this batch, since the batch was first distributed in December 2022. Whilst preliminary investigations indicate that this contamination is not widespread further investigations are necessary and ongoing. Bristol Laboratories consider it necessary however, to conduct a precautionary recall of the batch whilst such investigations are ongoing.

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. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Never stop taking medicines such as phenobarbital without medical advice, especially if they are being used for epilepsy. Suddenly stopping an epilepsy medicine may cause your seizures to start again or happen more often or last longer than before.

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](#).



Medicines & Healthcare products
Regulatory Agency

Further Information

For medical information enquiries please contact: Notifications@bristol-labs.co.uk

For stock control enquiries please contact: Notifications@bristol-labs.co.uk

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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