



# MEDICINES RECALL

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Pharmacy/Wholesaler Level Recall

Date: 13 June 2022

EL (22)A/28

Our Ref: MDR 215-01/22

Dear Healthcare Professional,

## BRISTOL LABORATORIES LIMITED

### Phenobarbital 60 mg Tablets

**PL 17907/0177**

Batch Number	Expiry Date	Pack Size	First Distributed
NW0001	December 2022	28	30 September 2020

Active Pharmaceutical Ingredient: Phenobarbital

### Brief description of the problem

Bristol Laboratories Limited are recalling the above batch of product as a precautionary measure due to low dissolution test results reported during ongoing stability studies.

### 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 medicines from this batch, as stopping phenobarbital treatment abruptly is likely to cause harm.
- Never stop taking medicines such as phenobarbital without medical advice. Suddenly stopping an epilepsy medicine may cause your seizures to start again or happen more often or last longer than before.
- 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 [notifications@bristol-labs.co.uk](mailto: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

**Defective Medicines Report Centre**

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**London**

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