Medicines & Healthcare products
Regulatory Agency

M E D I C I N E S R E C A L L

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 10 July 2023 | EL (23)A/23 | Our Ref: MDR 008-07/23

Dear Healthcare Professional

Tillomed Laboratories Limited

Labetalol 200mg Tablets **PL 11311/0376**

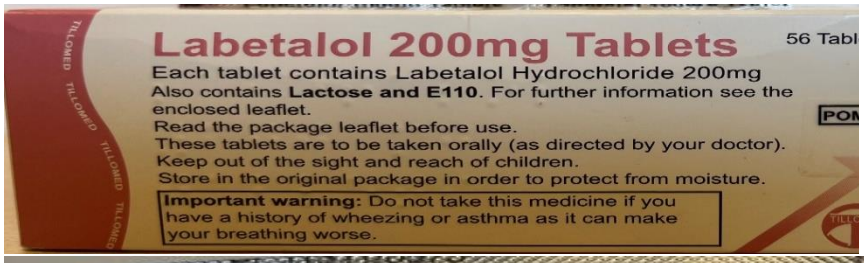
SNOMED Code 36537111000001109

Batch Number	Expiry Date	Pack Size	First Distributed
221345	08/2025	56 (4x14)	15/05/2023

Active Pharmaceutical Ingredient: Labetalol hydrochloride

Brief description of the problem
Tillomed Laboratories Limited is recalling one batch of Labetalol 200mg Tablets due to an error on the foil blister packaging. The incorrect aluminium foil blister packaging states Labetalol 100mg Tablets, however it should be labelled as Labetalol 200mg Tablets. This error has occurred at the primary packing operation. The description on the carton of a strength of 'Labetalol 200mg Tablets' is correct.

Tillomed Laboratories Limited has confirmed the actual tablet contained in the blister is Labetalol 200mg Tablets, which is the strength stated on the outer carton. This error is limited to the packaging of the batch with 100mg aluminium foil blister and does not impact the lot (batch) number or expiry as printed on the outer carton and aluminium foil blister. The images below show the error on the incorrect aluminium foil blister packaging and show the correctly labelled cartons and batch/lot number and expiry date.



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.

This recall is at pharmacy and wholesaler level and not directed to patient level. However, patients may present with the incorrectly labelled aluminium foil blister. Pharmacy teams should exercise their professional judgement to supply the correct pack, however there is no impact to the overall tablet, as Tillomed Laboratories Limited have confirmed that all blisters for this batch contain the 200mg strength tablets. If the prescription was written within 6 months, pharmacists can arrange for the dispensing of a pack that does not contain the incorrect blister foil labelling.

Advice for patients
Labetalol 200mg tablets are used to treat high blood pressure and angina with high blood pressure. One batch of Labetalol made by Tillomed Laboratories Limited has an error on the foil blister inside the pack. The foil blister says that it contains Labetalol 100mg. This is incorrect. It actually contains 200mg of Labetalol. Tillomed Laboratories Limited has confirmed the quality and safety of the tablets has not been affected.

The carton (box) that the medicine comes in is correct and says Labetalol 200mg tablets. The carton will also show the lot (batch) number of 221345. This is the only batch of Labetalol affected by the error.

If you were prescribed Labetalol 200mg and have a pack that contains a blister that states Labetalol 100mg Tablet on the foil blister (which matches with batch/lot number 221345 and expiry date of 08/2025), the tablets inside will be Labetalol 200mg Tablets as per your prescription. You can check the tablet, which should match the description as detailed in the Patient Information Leaflet. The Labetalol 200mg Tablet is "Orange, round biconvex film-coated tablet coded LTL 200" on one side.

If you have an incorrectly labelled blister as mentioned in this notification or you have any concerns, please contact your pharmacist directly who can advise and arrange for a replacement. If the prescription was written within 6 months, the pharmacist will arrange for the dispensing of a pack that does not contain the incorrect blister foil labelling, otherwise you may need to seek advice from your GP for a further prescription.

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.

If you have accidentally taken too many tablets, please seek immediate medical advice. Remember to take the leaflet that came with your medicine and any remaining tablets with you, Symptoms of overdose include low blood pressure (hypotension), slower heartbeat (bradycardia), difficulty in breathing or wheezing (bronchospasm), drowsiness, confusion, seizures, hallucinations, and dilated pupils

Further Information
For all medical enquiries, please contact medical information at Tillomed Laboratories Limited by email to medical.information@tillomed.co.uk or PVUK@tillomed.co.uk or by telephone +44 (0)1480 402 400

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.

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Yours faithfully

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