Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 29 October 2024 EL (24)A/52 Our Ref: DMRC-33718718

Dear Healthcare Professional

Tillomed Laboratories Limited

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

SNOMED Code 36537111000001109

Batch Number	Expiry Date	Pack Size	First Distributed
240537	02/2027	56 (4x14)	21/05/2024

Active Pharmaceutical Ingredient: Labetalol hydrochloride

Brief description of the problem
Tillomed Laboratories Limited is recalling one batch of Labetalol 200mg Tablets as a precautionary measure due to potential mix-up at the manufacturing site. Please note this is a Class 2 Patient, Pharmacy and Wholesaler level recall. A limited number of Labetalol 200mg Tablets (Batch Number 240537) cartons may contain a blister strip of Vera-Til SR 240mg Tablets, (verapamil), PL 11311/0078 (Batch Number 240750) with the blister strips of Labetalol 200mg Tablets. Both products were manufactured at the same manufacturing site and the error appears to have occurred during secondary packaging of the blister strips into the cartons.

Tillomed Laboratories have received one single market complaint where a blister strip of Vera-Til SR 240mg Tablets (Batch Number 240750) was found with the blister strips of Labetalol 200mg Tablets (Batch Number 240537). There have been no other similar reports related to this batch, since the batch was first distributed in May 2024.This means that a limited number of packs could contain the incorrect medicine, therefore the product is being recalled as a precautionary measure.

The images show the incorrect blister of Vera-Til SR 240mg Tablet found inside the carton of Labetalol 200mg Tablets.

Advice for healthcare professionals
Stop supplying the above product immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

1. Pharmacists should identify and immediately contact all patients who have been dispensed the impacted batch and ask them to confirm if they have remaining stock within their possession. If batch traceability information is not available, all patients dispensed this product from May 2024 should be contacted. Patients should be advised to check for this batch number and return any packs that contain the incorrect blister strips to their pharmacy.

   If the pharmacist identifies any patients with an impacted product, they should also consider contacting the patient's GP or prescriber and discuss if a new prescription is required for any ongoing resupply with other labetalol products.

2. Prescribers, clinicians, and other healthcare professionals involved in the prescribing/monitoring of patients who may have taken verapamil instead of labetalol, should contact their patients and/or carers directly to ensure that their treatment is reviewed, and a suitable alternative product is prescribed.

As patients may require monitoring, other clinicians and healthcare professionals may need to be involved. Healthcare professionals should be aware that only the batch stated in this notification is impacted.

The Department of Health and Social Care (DHSC) has confirmed that, as this is a prescription only medicine, a new prescription will be required for the dispensing of a replacement product. Some patients who have received this product will be entitled to free prescriptions through existing exemptions,or have arrangements in place for a pre-payment certificate and therefore a new prescription will not incur any additional costs. Where patients pay for NHS prescriptions, a charge for the new prescription will apply; patients may contact the Defective Medicines Reporting Centre if further information is required.

Advice for patients
One batch of Labetalol 200 mg Tablets, manufactured by Tillomed Laboratories Limited, may contain the incorrect medication and is being recalled as a precautionary measure. Tillomed Laboratories have received one single market complaint where a blister strip of Vera-Til SR 240mg Tablets (Batch Number 240750) was found with the blister strips of Labetalol 200mg Tablets (Batch Number 240537).
There have been no other similar reports related to this batch, since the batch was first distributed in May 2024.This means that a limited number of packs could contain the incorrect medicine, therefore the product is being recalled as a precautionary measure.

If you were prescribed Labetalol 200mg Tablets and have received the impacted product batch (Batch Number 240537) please check that the product contains the correct medication. The batch number and expiry date information can be found on outer carton and also on the blister strips directly. If you are unsure or have any questions, please seek advice from your pharmacy or other healthcare professionals responsible for your care.

If you previously received this batch, (where known) or if you have accidentally taken Vera-Til SR 240mg Tablets please seek immediate medical advice. Please take the leaflet that came with your medicine and any remaining tablets with you. The tablet descriptions, as stated in the Patient Information Leaflets are listed below:

- **Labetalol 200mg Tablets: Orange round biconvex film-coated tablet coded "TLT 200" on one side**

- **Vera-Til SR 240mg Tablet: Oblong, light green, modified release, film-coated tablet with the score on both sides and smooth intact surface.**

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 all medical enquiries, please contact Tillomed Laboratories Limited by email at either medical.information@tillomed.co.uk or PVUK@tillomed.co.uk, or telephone 0800 9706115.

For enquiries relating to stock returns please email Tillomed Laboratories Limited customer services customer.service@tillomed.com or telephone 01480 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.

Yours faithfully

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