Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/32

Caution In Use

Issued 01 July 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Amdipharm UK Ltd

MEDICINE DETAILS

Erythromycin Stearate BP 250mg Tablets (Erythrocin 250 Tablets)

PL: 20072/0036

Active Ingredient: Erythromycin Stearate

SNOMED code: 274611000001103

GTIN: 05060064171240

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
6104532	08/2028	100 Tablets/pack	04/09/2024

Background

Amdipharm UK Ltd has informed MHRA that the Patient information leaflet (PIL) in the cartons for the batch listed in this notification includes a superseded PIL. The superseded PIL used in Batch 6104532 is missing important updated safety information, as per the recommendation from Pharmacovigilance Risk Assessment Committee (PRAC).

Amdipharm UK Ltd has confirmed that 4515 packs of the affected batch are already distributed in the market and 6823 packs are awaiting distribution. Due to supply considerations the remaining packs (6823 units) will continue to be distributed. The updated PIL is available on the website of electronic medicines compendium (eMC): https://www.medicines.org.uk/emc/files/pil.403.pdf

The missing information from latest PIL is presented below:

2. What you need to know before you take Erythrocin® Tablets

Do not take Erythrocin® Tablets:

- if you are currently taking a medicine called:

- lomitapide (used to lower increased blood fats such as cholesterol and triglycerides). Taking this medicine at the same time as erythromycin may lead to a rise in enzymes produced by liver cells (transaminases), which indicates that the liver is under stress and may lead to liver problems.

Other medicines and Erythrocin® Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

This is especially important if you are taking medicines from the following families:

• corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions).

Pregnancy and breast-feeding

The active ingredient of Erythrocin® film-coated tablet may cross the placenta in pregnant women and is excreted in breast milk. Information from studies regarding the risk of birth defects is inconsistent, but some studies have reported heart defects following Erythrocin® film-coated tablet use in early pregnancy.

Advice for Healthcare Professionals:

There is no risk to product quality or impact to safety of the medicines listed in this notification because of this missing information. Healthcare professionals are advised to review the information contained within this notification and take this into account when dispensing this product.

If the medicines listed in this notification are dispensed, ensure that patients are aware of the missing information. Hard copies of the correct PIL will be provided by the Marketing Authorisation Holder upon request, so that any of the affected packs remaining in the dispensary can be supplemented with the correct PIL.

Amdipharm UK Ltd can provide printed copy of an updated PIL to HCP's via medicalinformation@advanzpharma.com or telephone +44 (0) 208 588 9131.

Advice for Healthcare Professionals to Provide to Patients:

Patients should be aware that some packs of Erythromycin Stearate BP 250mg Tablets (Erythrocin 250 Tablets) Batch 6104532 contain the incorrect Patient Information Leaflet (PIL). The missing safety information is listed in this notification and if you have any additional concerns relating to this information, please contact your pharmacist or prescriber.

The missing information, summarised in this notification, does not change or affect the quality of the product. Patients can continue to safely take this medicine unless they have concerns related to the missing information.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For medical information enquiries please email medicalinformation@advanzpharma.com, or telephone +44 (0) 208 588 9131

For stock control enquiries please email custcustomercare@advanzpharma.com or telephone 0208 588 9441

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