Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/48

Caution In Use

Issued 12 November 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Star Pharmaceuticals Ltd

MEDICINE DETAILS

Enalapril maleate/Hydrochlorothiazide 20 mg/12.5 mg Tablets

PLPI: 20636/1651

Active Ingredient: enalapril maleate / hydrochlorothiazide

GTIN: 05050114165107

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
Y018198	30/06/2027	28	22/09/2026
Y019635	31/10/2027	28	05/12/2025
C125483	29/02/2028	28	05/03/2026
C135541	30/11/2028	28	08/06/2026

Background

Star Pharmaceuticals Limited have informed the MHRA of a typographical error on the strength of hydrochlorothiazide printed on the front face of the carton which incorrectly states “12. mg” instead of “12.5 mg”. The strength is correctly presented on all other faces of the carton, the leaflet and the blister foil. The volume of affected stock distributed to the UK market is 1740 packs.

Advice for Healthcare Professionals:

Healthcare professionals are asked to note the information in this notification and should continue to dispense this product; the quality of the tablets is not impacted by this labelling defect.

The risk associated with the labelling error is considered low because no corresponding strengths of the enalapril maleate / hydrochlorothiazide combination where the hydrochlorothiazide strength is expressed as 12 mg exist.

Healthcare professionals are advised to reassure patients, if contacted, that the product is enalapril maleate 20 mg / hydrochlorothiazide 12.5 mg tablets as described in the Patient Information Leaflet.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take this medication as prescribed. This does not affect the quality of the tablets.

If you are unsure or have any questions, please seek advice from your pharmacy or other healthcare professionals involved in your treatment.

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 all medical information enquiries and information on this product, please email info@drugsrus.co.uk or telephone 020 8423 2111.

Recipients of this Medicines Notification 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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