

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/33 Caution In Use

Issued 03 July 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Crescent Pharma Ltd.

MEDICINE DETAILS

Simvastatin 10mg Tablet

PL: 20416/0153

Active Ingredient: Simvastatin

SNOMED code: 9805211000001109

EAN: 5055382303046 GTIN: 05017123000348

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed	Livery
A24228	APR 2027	28 Tablet	05-Feb-2025	Almus

Background

Crescent Pharma Limited has informed the MHRA of an error with the European Article Number (EAN) barcode on the cartons of the above batch of Simvastatin 10 mg Tablets distributed by Alliance Healthcare UK. When scanned, the EAN barcode identifies the product as Paracetamol 250mg/5ml Oral Solution. The other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct. The quality of the medicine is not impacted by the labelling defect.

Advice for Healthcare Professionals:

Do not to use this batch of medicine in robotic or automated dispensing or stocking systems. Carry out manual dispensing and stocking, as appropriate. Product quality of the Simvastatin 10mg Tablets is not impacted by this issue, therefore the affected batches are not being recalled.

Advice for Healthcare Professionals to Provide to Patients:

No action is needed from patients, continue to take medication from this batch as prescribed by your healthcare professional. The issue is related to the wrong barcode on the cartons of the listed batch of Simvastatin 10mg Tablets and will be controlled by the healthcare professionals prescribing/dispensing the medication. The quality of the medication is not affected.

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 medinfo@crescentpharma.com, for reporting of side effects email safety@crescentpharma.com or telephone +44 1217901596.

For stock control enquiries please email Sean.McCaul@alliance-healthcare.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 10 South Colonnade Canary Wharf London E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk