



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 3 June 2024

EL (24)A/18

Our Ref: MDR 142-05/24

Dear Healthcare Professional,

Manx Healthcare Ltd.

Betamethasone Valerate 0.1% Ointment

PL 14251/0010

SNOMED Code: 41207211000001102

Batch No	Expiry Date	Pack Size	First Distributed
G0039	Feb-2027	30g	April 2024

Active Pharmaceutical Ingredient: Betamethasone valerate

Brief description of the problem

Manx Healthcare Ltd. has informed MHRA that they have identified a problem with the product packaging of the batch indicated in the table. The tamper-evident seal on the outer carton may be missing or deformed on some packs. This is due to an intermittent equipment fault during secondary packaging.

Advice for healthcare professionals

The quality of the ointment is not impacted by the defect. Any packs from this batch of product with missing or deformed seals may be dispensed. Healthcare professionals dispensing this medication may wish to advise patients that the seal on the outer carton may be broken but this will not affect product quality.

Advice for patients

The quality of the ointment is not impacted by the manufacturing issue as it only affects the outer carton. The tube of ointment that the patient receives will be sealed. Patients should continue to take medicines from this batch as prescribed by your healthcare professional.

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 medical information enquiries please contact medinfo@manxhealthcare.com, or telephone: +44 (0)1926 482511.

For stock control enquiries please contact customerservice@manxhealthcare.com, or telephone: +44 (0)1926 482511.

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.



Medicines & Healthcare products
Regulatory Agency

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk