MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/27

Caution In Use

04 June 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Teva UK Ltd

MEDICINE DETAILS

Ponlimsi (Denosumab) 60mg Solution for Injection in Pre-filled Syringe

PL: 00289/2645

Active Ingredient: denosumab

SNOMED code: 45668211000001103

GTIN: 5017007608233

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
184472	30/11/2028	1 pre-filled syringe	21/01/2026
186711	30/11/2028	1 pre-filled syringe	21/04/2026
188656	28/02/2029	1 pre-filled syringe	01/06/2026

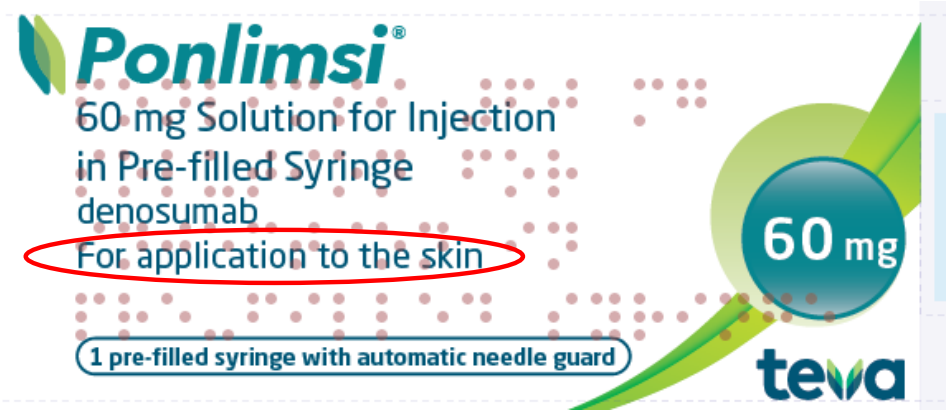
Background

Teva UK Limited is reporting a labelling error on the carton for Ponlimsi (Denosumab) 60mg Solution for injection in Pre-filled Syringe. The carton states “For application to the skin” when the product is licensed for subcutaneous use.

This notification contains batches that have commenced distribution from 21/01/2026 onwards All 3 batches have been manufactured and packed with the erroneous carton, however as the product administration should be performed by an individual who has been adequately trained in injection techniques, these batches will not be repackaged and continue to be distributed. Teva UK Limited have confirmed that all future deliveries will be

supplied with a copy of this notification to help remind healthcare professionals and patients that this product is for subcutaneous use.

This error is circled in red on the image below:



Advice for Healthcare Professionals:

There is no risk to product quality as a result of this labelling error. Aside from the labelling error, no additional errors have been identified with the product or delivery device, therefore the affected batches are not being recalled.

Healthcare professionals are advised to reassure patients, if contacted, that the product is for subcutaneous injection as described in the Patient Information Leaflet, which contain clear instructions for intended use.

The Summary of Product Characteristics and Patient Information Leaflet can be accessed at the following website https://products.tevauk.com/hcp/denosumab-823?productId=27077

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to use syringes from these batches as prescribed by your healthcare professional. This does not affect the quality of the medicine. The cartons contain a syringe for subcutaneous injection as prescribed, and this is a labelling error.

If you have concerns about a medicine you may be using, please contact your healthcare professional.

Commented [AW1]: Wondering if instead we say something like "No action is needed from patients as this product is administered by healthcare professionals who will manage the issue."

Commented [DM2R1]: This product can be self administered therefore we believe the wording we have included is more appropriate for an independent patient. I hope this is agreeable.

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@tevauk.com

For stock control enquiries please email Customer.services@tevauk.com

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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