MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/47 Action within 5 days

Issued 10 November 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Zambon SpA

MEDICINE DETAILS

Emylif 50mg orodispersible film

PL: 31654/0013

Active Ingredient: riluzole

SNOMED code: 42121311000001106

GTIN: 8031609001824

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
C24QA104	04-2027	56 sachets	13/05/2025

Background

Ongoing stability testing identified out of specification results for unknown impurities at the 24-month stability timepoint for one batch of Emylif films. Emylif films were previously licensed with a 36-month shelf life.

The batch of Emylif 50mg orodispersible film specified in the table is being recalled as a precautionary measure before it reaches 24 months since the date of manufacture (C24QA104 would reach the 24-month timepoint on 30 April 2026).

Out of an abundance of caution, subsequent batches of Emylif 50mg orodispersible film, are labelled with an 18-month shelf life.

This recall is at pharmacy and wholesaler level.

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Advice for Healthcare Professionals:

Stop supplying the specified batch immediately. Quarantine all stock from this batch and return it to your supplier using your supplier's approved process. The batch is being recalled at pharmacy and wholesaler level early as a precautionary measure. Other batches are not affected and may be supplied as per the printed expiry date.

Advice for Healthcare Professionals to Provide to Patients:

No further action is required by patients as this is a pharmacy and wholesaler level recall. Patients should continue to take medicines from batch C24QA104 as prescribed by the healthcare professional. This batch will remain within specification limits until 30 April 2026.

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.

Additional information:

For all medical information enquiries and information on this product, please email infoUK@zambongroup.com, or telephone + 44 (0)800 0288 942.

For stock control enquiries please email <u>infoUK@zambongroup.com</u>, or telephone + 44 (0)800 0288 942.

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

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