MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT NOTIFICATION, EL(26)A/36

Caution In Use

Issued 23 July 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Neuraxpharm UK Ltd.

MEDICINE DETAILS

Tuzulby 20 mg prolonged-release chewable tablets

PL: 49718/0143

Active Ingredient: methylphenidate hydrochloride

SNOMED code: 45484411000001107

GTIN: 8436027473978

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
77951	08/2028	30	18/12/2025
79949	02/2029	30	22/06/2026

MEDICINE DETAILS

Tuzulby 30 mg prolonged-release chewable tablets

PL: 49718/0144

Active Ingredient: methylphenidate hydrochloride

SNOMED code: 45485411000001108

GTIN: 8436027473985

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
78001	08/2028	30	18/12/2025
79961	02/2029	30	22/06/2026

MEDICINE DETAILS

Tuzulby 40 mg prolonged-release chewable tablets

PL: 49718/0145

Active Ingredient: methylphenidate hydrochloride

SNOMED code: 45485711000001102

GTIN: 8436027473992

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
78011	08/2028	30	18/12/2025
79974	02/2029	30	22/06/2026

Background

Neuraxpharm UK Ltd has informed the MHRA of missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for the above batches of Tuzulby prolonged release 20mg, 30mg and 40mg chewable tablets.

The missing safety information relates to epistaxis (nosebleed). The omitted information concerns addition of epistaxis (frequency not known) as an adverse reaction within the Summary of Product Characteristics and Patient Information Leaflet, specifically:

Summary of Product Characteristics (SmPC)

Section 4.8 - ‘Respiratory, thoracic and mediastinal disorders’ with a frequency of ‘*not known*’ – **Epistaxis**.

Patient Information Leaflet (PIL)

Section 4 – ‘Possible side effects’. Other side effects including the following, if they get serious, please tell your doctor or pharmacist:

Not known (frequency cannot be estimated from the available data) – **Nosebleed**.

Advice for Healthcare Professionals:

Healthcare professionals are advised to be aware that epistaxis (nosebleed) is a recognised adverse reaction associated with Tuzulby prolonged release chewable tablets and has been added to the Summary of Product Characteristics and Patient Information Leaflet with a frequency of ‘not known’.

Healthcare professionals should continue to prescribe and dispense Tuzulby prolonged release chewable tablets in accordance with the approved product information. Patients reporting epistaxis should be managed in accordance with routine clinical practice and the individual patient's clinical circumstances.

A corrected version of the Patient Information Leaflet, containing the required information, is available on the MHRA Products website. Upon request, Neuraxpharm UK Ltd will provide hard copies of the updated PIL to wholesalers and pharmacies so that any packs can be supplemented with the correct PIL information. Updated Summary of Product Characteristics are also available for the 20mg, 30mg, and 40mg products.

Advice for Healthcare Professionals to Provide to Patients:

The Patient Information Leaflet is being updated to include nosebleed (epistaxis) as a possible side effect. If you experience nosebleeds or have any concerns about your treatment, please speak to your doctor or pharmacist.

Patients should continue to take Tuzulby prolonged release chewable tablets as prescribed by their healthcare professional. Do not stop treatment without seeking medical advice. 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-uk@neuraxpharm.com, or telephone +44 (0) 330 128 0919. For stock control enquiries please email info-uk@neuraxpharm.com, or telephone +44 (0) 118 211 4039.

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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