Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/39

Caution In Use

Issued 07 August 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Zydus Pharmaceuticals UK Ltd

MEDICINE DETAILS

Topiramate Zydus Pharmaceuticals UK 20mg/ml Oral Solution
PL: 58839/0026
Active Ingredient: topiramate
SNOMED code: 44000111000001109
GTIN: 5070003280124 (150ml Bottle); 5070003280131 (280ml Bottle)

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
TPR24001	Jun-26	280ml	11/Nov/2024
TPR24002	Jun-26	280ml	11/Nov/2024
TPR24003	Sep-26	150ml	29/Nov/2024

Background

Zydus Pharmaceuticals UK LTD has informed the MHRA that there is an error on the artwork for the outer carton and Patient Information Leaflet (PIL) of Topiramate Zydus Pharmaceuticals UK 20mg/ml Oral Solution (pack size 150ml and 280ml bottles). The instruction for use is missing the step to shake well prior to opening and before each use. These packs are Prescription Only Medicines (POM) and are intended for use in both adult patients and paediatric patients.

Advice for Healthcare Professionals:

Healthcare professionals and retailers are advised to review the information contained within this notification and, where possible, inform customers that Topiramate Zydus Pharmaceuticals UK 20mg/ml Oral Solution (Pack Size 150ml and 280ml bottles) should be “shaken well prior to opening and before each use”.

Healthcare professional should continue to prescribe and dispense the product as the batches listed are not being recalled.

Advice for Patients:

Please shake the bottle prior to opening and before each use. Patients in receipt of these batches should continue to take the medicine as prescribed by your healthcare professional. Never stop taking medicines such as topiramate without medical advice, especially if they are being used for epilepsy. Suddenly stopping an epilepsy medicine may cause your seizures to start again or happen more often or last longer than before. These batches are not being recalled and should not cause harm if taken without shaking

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 enquires on this product please email DrugSafety@ZydusUK.com or telephone 0800 9956034.

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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