



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level

Date: 08 June 2020

EL (20)A/25

Our Ref: MDR 115-03/20

Dear Healthcare Professional,

Torbay Pharmaceuticals (for Veriton Pharma Ltd)

**Epistatus (Midazolam) 10mg/mL Oromucosal
Solution (Multi Dose Bottles)**

**Unlicensed Medicine -
MS13079**

Batch Number	Expiry Date	Pack Size	First Distributed
191111C	31/11/2021	5mL in 30mL bottle	20/04/2020
200113C	31/01/2022	5mL in 30mL bottle	30/03/2020

Active Pharmaceutical Ingredient (Midazolam)

Brief description of the problem

Torbay Pharmaceuticals has informed us that the child-resistant container closure for Epistatus 10mg/mL Oromucosal Solution (Multi Dose Bottles) may be faulty and incorrectly engaged. The child resistant closure can potentially be removed without unscrewing the cap closure. Removal of an incorrectly engaged cap closure will result in the yellow tamper evident band not being retained on the neck of the bottle. It should be noted that this product is manufactured as an unlicensed special.

Advice for healthcare professionals

Healthcare professionals are advised to stop supplying the above products immediately and quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Further Information

For stock control queries please contact Veriton Pharma Ltd., Telephone +44 (0)1932 690325 or email info@veritonpharma.com

For any medical information enquires please contact Veriton Pharma Ltd., Telephone +44 (0)1932 690325 or email info@veritonpharma.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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