Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 30 August 2023 EL(23)A/32 Our Ref: MDR 047-08/23

Dear Healthcare Professional,

Veriton Pharma Limited

Epistatus 2.5 mg oromucosal solution, pre-filled syringe (PFS) PLGB 16786/0015

SNOMED Code: 41927911000001101

Batch No	Expiry Date	Pack Size	First Distributed
230327A2	09/2024	1 x 0.25ml PFS	05/06/2023

Active Pharmaceutical Ingredient: Each pre-filled oral syringe contains 0.25ml of midazolam maleate corresponding to 2.5mg midazolam.

Brief description of the problem
Veriton Pharma Limited is recalling a specific batch of Epistatus (midazolam) 2.5mg Oromucosal Solution (pre-filled oral syringes) due to confirmed out of specification results related to the product appearance. Following a market complaint, the batch listed in this notification was investigated and it was confirmed that there is potential for some products to appear cloudy and/or contain crystalline particles. The Summary of Product Characteristics (SmPC) states that the product should be a '*clear colourless to pale yellow solution*.' Additionally, there is specific information that states '*do not use if the solution is not clear (e.g. cloudy or white particles are present).*'

SmPC: Epistatus 2.5 mg oromucosal solution, pre-filled syringe

Advice for healthcare professionals
Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Healthcare settings should consider using other batches or midazolam from alternative providers to administer emergency doses as required. The opalescent product in the impacted batch has been shown to contain sufficient midazolam and could be used in an emergency where alternate medicine is not available. The recall is being carried out as a precautionary measure to mitigate any further concerns with syringes that are not as described in the SmPC.

Advice for patients and carers
One batch of Epistatus (midazolam) 2.5mg oral syringes has been recalled from pharmacies as a precaution due to the potential for cloudiness or crystallisation.

Patients and carers do not need to return this medicine but are reminded of the importance of following the instructions in the Patient Information Leaflet (PIL) related to checking the physical appearance of the product before use. Do not use or give this medicine if you notice that the syringe has been damaged or

if the solution is not clear (for example, it is cloudy or white particles are present). In an emergency, please contact the emergency services if you have any concerns.

A copy of the Patient Information Leaflet (PIL) can be found in the product packaging or obtained from PIL: Epistatus 2.5mg (Midazolam) Oromucosal Solution

Patients and carers are always advised to follow the information within the PIL on what to do if the patient's condition does not improve:

- Seek emergency medical assistance – telephone for an ambulance immediately – if the patient's seizure does not stop shortly after administering Epistatus.
- Follow the instruction you have received from the patient's doctor on how to act in this situation. A second dose of Epistatus should not be given without medical advice.

If the patient's condition improves but the seizure ('fit') then starts again or if you give more Epistatus that you should:

- Seek emergency medical assistance – telephone for an ambulance immediately.
- Further guidance on signs and symptoms to look out for is available in the Patient Information Leaflet, however patients and carers should always contact the emergency services in all circumstances: PIL: Epistatus 2.5mg (Midazolam) Oromucosal Solution

If you are taking this batch of product and you experience any adverse reactions or insufficient control of symptoms, please seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
For medical information enquiries please contact Veriton Pharma Limited by emailing to centralmedicalinformation@veritonpharma.com or via the direct line: +44 (0)1932 690325. For stock control enquiries please contact Veriton Pharma Limited by emailing to orders@veritonpharma.com

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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