Chief Medical Officer Directorate Pharmacy and Medicines Division



29 February 2024

Medicine Supply Alert Notice

Midazolam (Epistatus[®]) 5mg/0.5ml oromucosal solution pre-filled oral syringes

Priority: Level 2^{*} Valid until: TBC

Issue

- 1. Midazolam (Epistatus[®]) 5mg/**0.5ml** oromucosal solution pre-filled oral syringes are currently out of stock. Resupply date of this product is to be confirmed.
- 2. Midazolam (Buccolam[®] and generic) 5mg/**1ml** oromucosal solution pre-filled oral syringes remain available and can support increased demand.

Advice and Actions

- 3. Until the shortage resolves, prescribers should:
 - not initiate new patients on Epistatus[®] 5mg/0.5ml oromucosal solution pre-filled oral syringes; and
 - consider prescribing midazolam (Buccolam[®] or the generic) 5mg/**1ml** oromucosal solution pre-filled oral syringes where appropriate, ensuring that the parent/carer is advised on the change in volume being administered, counselled on how to administer the dose, and shown the patient information leaflet (see Supporting Information below).

Additional Information

Clinical Information

- Epistatus[®] 5mg/0.5ml is licensed for the treatment of prolonged, acute, convulsive seizures in children aged from 1 year to < 5 years.
- 5. Buccolam[®]/generic midazolam 5mg/1ml oromucosal solution pre-filled oral syringes are licensed for the same indication and for use in the same age groups but are formulated so that the 5mg dose is in twice the volume of Epistatus[®], and also differ in administration technique. It is good practice to prescribe midazolam oromucosal solution by brand name and express strength in both milligrams and millilitres.

Please refer to the links below for further information:

- SmPCs: Midazolam oromucosal solution
- BNFc: Repeated or cluster seizures, prolonged seizures, and status epilepticus
- BNF Midazolam
- Patient Information Leaflet: Buccolam
- SmPCs and PILs: generic midazolam oromucosal solution

Specialist Pharmacy Service (SPS) website

- 6. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 7. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scotlish context.

Enquiries

 Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <u>PharmacyTeam@gov.scot</u> (primary care) or <u>NSS.NHSSMedicineShortages@nhs.scot</u> (secondary care).