



29 September 2023

## **Medicine Supply Alert Notice**

### **Midazolam (Epistatus®) 2.5mg/0.25mL and 10mg/1mL oromucosal solution pre-filled oral syringes**

**Priority: Level 2\***  
**Valid until: late November 2023**

#### **Issue**

1. Midazolam (Epistatus®) 2.5mg/0.25mL and 10mg/1mL oromucosal solution pre-filled oral syringes are **out of stock** until late November 2023.
2. Midazolam (Buccolam®) 2.5mg/0.5mL and 10mg/2mL oromucosal solution pre-filled oral syringes remain available and will be able to support increased demand.
3. Generic midazolam 2.5mg/0.5mL oromucosal solution pre-filled oral syringes remain available and will be able to support increased demand.
4. Generic midazolam 10mg/2ml oromucosal solution pre-filled oral syringes remain available but are unable to support an increase in demand.

#### **Advice and Actions**

5. Until the shortage resolves, prescribers should:
  - not initiate new patients on Epistatus® 2.5mg/0.25mL or 10mg/1mL oromucosal solution pre-filled oral syringes; and
  - consider prescribing Buccolam® 2.5mg/0.5mL or Buccolam® 10mg/2mL 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 Additional Information below for links to the materials).
  - In the event that Buccolam® 2.5mg/0.5mL oromucosal solution pre-filled oral syringes become unavailable consider prescribing generic midazolam 2.5mg/0.5mL oromucosal solution pre-filled oral syringes.

#### **Additional Information**

##### **Clinical Information**

6. Epistatus® is indicated for the treatment of prolonged, acute, convulsive seizures. The 2.5mg/0.25mL strength is licensed for use in infants between 3-6 months of age in the hospital setting and the 10mg/1mL for use in children and adolescents from age 10 years to < 18 years.

7. Buccolam<sup>®</sup>/generic midazolam oromucosal solution pre-filled oral syringes 2.5mg/0.5mL and 10mg/2mL are licensed for the same indication and age groups as Epistatus<sup>®</sup> but are formulated in twice the volume of Epistatus<sup>®</sup>, 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.
8. **Please note an [MHRA medicine recall](#) was issued for Epistatus<sup>®</sup> 2.5mg/0.25mL oromucosal solution, prefilled syringes on 30<sup>th</sup> August 2023.**

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**

9. 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.
10. To access the online Medicines Supply Tool you need to register with the [SPS website](#). 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.
11. 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.
12. 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 Scottish context.

### **Enquiries**

13. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).