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Medicine Supply Notification: Midazolam (Epistatus®) 2.5mg/0.25ml and 10mg/1ml oromucosal solution pre-filled oral syringes

Tier 2 – medium impact*

Date of issue: 14/09/2023

[Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

Summary

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

Actions Required

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 midazolam (Buccolam® or the generic) 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 Supporting Information below).

Supporting Information

Clinical Information

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.

Buccolam®/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® but are formulated 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 note an MHRA medicine recall was issued for Epistatus® 2.5mg oromucosal solution, pre-filled syringes on 30th August 2023.

[MPS 2053 \(hscni.net\)](https://www.hscni.net/mips/2053)

Please refer to the links below for further information:

- SmPCs: Midazolam oromucosal solution [Search Results - \(emc\) \(medicines.org.uk\)](#)
- BNFC: Repeated or cluster seizures, prolonged seizures, and status epilepticus [Epilepsy | Treatment summaries | BNFC | NICE](#)
- BNF Midazolam [Midazolam | Drugs | BNF | NICE](#)
- Patient Information Leaflet: Buccolam [BUCCOLAM PSUSA-10118-201909 - EN PI \(clean\) \(medicines.org.uk\)](#)
- SmPCs and PILs: generic midazolam oromucosal solution [Search Results - \(emc\) \(medicines.org.uk\)](#)