



Medicine Supply Notification

MSN/2023/086

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

Link: [Medicines Supply Tool](#)

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.

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

Please note an [MHRA medicine recall](#) was issued for Epistatus® 2.5mg oromucosal solution, pre-filled syringes on 30th 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](#)

Enquiries

Enquiries from NHS Trusts in England should in the first instance be directed to your Regional Pharmacy Procurement Specialist, who will escalate to national teams if required.

REGION	Full Name	Email
Midlands	Andi Swain (East Midlands)	andi.swain@nhs.net
	Diptyka Hart (West Midlands)	Diptyka.Hart@uhb.nhs.uk
East of England	James Kent	james.kent@nhs.net
London	Jackie Eastwood	jacqueline.eastwood@gstt.nhs.uk
North East and Yorkshire	David Allwood (Yorkshire)	davidallwood@nhs.net
North West	Richard Bateman	richard.bateman@liverpoolft.nhs.uk
South East	Alison Ashman	Alison.Ashman@berkshire.nhs.uk
South West	Danny Palmer	danny.palmer@uhbw.nhs.uk

Scotland

nss.nhssmedicineshortages@nhs.scot

Wales

MedicinesShortages@gov.wales

Northern Ireland

RPHPS.Admin@northerntrust.hscni.net

All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2023/086

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.