



Medicine Supply Notification

MSN/2023/063

Diazepam 10mg/2.5ml rectal solution tubes

Tier 2 – medium impact*

Date of issue: 29/06/2023

Link: [Medicines Supply Tool](#)

Summary

- Diazepam 10mg/2.5ml rectal solution tubes will be out of stock from mid-July until mid-August 2023.
- Certain strengths of midazolam oromucosal solution pre-filled syringes remain available and will be able to support increased demand.
- Diazepam 5mg/2.5ml rectal solution tubes remain available and will be able to support increased demand.
- Where these are not suitable, unlicensed supplies of diazepam 10mg/2.5ml rectal solution tubes may be sourced, lead times vary.

Actions Required

Where supply of diazepam 10mg/2.5ml rectal solution tubes is not available, clinicians should:

- review patients and consider prescribing midazolam oromucosal solution which can support the market during this time, ensuring that the patient is not intolerant to any of the excipients and parent/carer is counselled on the appropriate dose and volume required, and advised on how to administer the dose;
- if midazolam oromucosal solution is not appropriate, consider prescribing diazepam 5mg/2.5ml rectal solution tubes to make up the dose required for the patient:
 - The parent or carer will need to be counselled on the number of rectal tubes to administer to make up the required dose and reminded that they will need to repeat this process for any subsequent doses;
- consider prescribing unlicensed diazepam 10mg/2.5ml rectal solution tubes only where licensed alternatives are not appropriate; and
- if the above options are not considered appropriate, advice should be sought from specialists for individualised review and consideration of alternative management options.

Ambulance service staff should:

- use diazepam 5mg/2.5ml rectal solution tubes to make up the dose required for the patient.

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

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

Supporting information

Clinical Information

Diazepam rectal solution tubes are licensed in epileptic and febrile convulsions, to relieve muscle spasm caused by tetanus, as a sedative in minor surgical and dental procedures, and for initial use in acute severe anxiety and agitation.

Midazolam oromucosal solution is licensed in the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children, and adolescents (from 3 months to < 18 years). Midazolam oromucosal solution is not licensed for use in children under 3 month or in adults over 18 years. It is used off-label for status epilepticus in these age groups.

The following midazolam oromucosal solution pre-filled syringes remain available and can support an uplift in demand:

- Midazolam 2.5mg/0.5mL oromucosal solution pre-filled syringes
- Midazolam 5mg/1mL oromucosal solution pre-filled syringes
- Midazolam 7.5mg/1.5mL oromucosal solution pre-filled syringes
- Midazolam 10mg/2 mL oromucosal solution pre-filled syringes

Guidance on ordering and prescribing unlicensed imports

- The following specialist importers have confirmed they can source unlicensed diazepam 10mg/2.5ml rectal solution tubes (please note there may be other companies that can also source supplies):
 - Orifarm
- Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),

Please refer to the links below for further information:

[SmPC Diazepam 5mg rectal solution](#)

[SmPC Midazolam oromucosal solution](#)

[BNF Diazepam](#)

[BNF Midazolam](#)

[BNFC: Repeated or cluster seizures, prolonged seizures, and status epilepticus](#)

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/2023/063

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.