HERPC
Hull & East Riding Prescribing Committee

Prescribing Framework for Midazolam Oromucosal Solution (Buccolam®) in Epilepsy in adults and children

Patient's Name:……..… NHS Number: ……

Patient's Address:……..……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:…….

Where prescriber is <u>not</u> a consultant,:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……... ……. Date:…….

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at : http://www.hey.nhs.uk/amber.htm

1. Background

These guidelines aim to provide a framework for the prescribing of **midazolam hydrochloride 5mg/ml oromucosal solution (Buccolam)** by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

2. Indication

Midazolam, is indicated for the management of *status epilepticus,* in both adults and children. Midazolam, administered via the buccal route (is normally used in situation of prolonged (lasting over 5 minutes or longer than usual) and/or recurrent seizures. It is used as an alternative to rectal diazepam as it is easier to administer. Prompt administration of treatment will significantly reduce the number of hospital admissions.

Midazolam is a Schedule 3 controlled drug (Misuse of Drugs Act 1971 & its regulations 2001)

3. Dose and administration

Age of patient	Dose of buccal midazolam
Child 1–2 months	300 micrograms/kg (max. per dose 2.5 mg) **HOSPITAL ONLY**
Child 3–11 months	2.5mg in 0.5ml
Child 1–4 years	5mg in 1ml
Child 5–9 years	7.5mg in 1.5ml
Child 10–17 years *	10mg in 2ml
Adult*	10mg in 2ml

*May increase to 15mg (in 3ml)
A single dose of buccal midazolam is generally sufficient to stop seizures in the majority of cases. A second dose* should only be given in accordance with patient's individual written care plan.
If no effect is apparent 10 minutes after dose given (or 5 minutes after second dose, where given), the ambulance service should be contacted.

The liquid can be given by squirting about half of the prescribed dose between the lower gum and the cheek on one side of the mouth and squirting the remaining liquid between the lower gum and the cheek on the other side of the mouth. However, if administration is difficult (e.g. if excessive salivation is a problem) the whole dose can be squirted into one side.

Doses above 10mg, use in patients below 3 months and over 18 years of age are outside current licence.

4. Duration of treatment

As advised by specialist, likely to be long-term.

5. Contraindications and cautions

Midazolam is contraindicated in patients with acute pulmonary insufficiency; marked neuromuscular respiratory weakness; sleep apnoea syndrome; unstable myasthenia gravis, CNS depression; compromised airway; severe respiratory depression
Use with caution in debilitated patients (reduce dose) (in adults); elderly (reduce dose) (in adults); history of alcohol dependence or abuse; history of drug dependence or abuse; myasthenia gravis; personality disorder (within the fearful group—dependent, avoidant, obsessive-compulsive) may increase risk of dependence; respiratory disease, cardiac disease; children (particularly if cardiovascular impairment); concentration of midazolam in children under 15 kg not to exceed 1 mg/mL; debilitated patients (reduce dose) (in children); hypothermia; hypovolaemia (risk of severe hypotension); neonates; risk of airways obstruction and hypoventilation in children under 6 months (monitor respiratory rate and oxygen saturation); vasoconstriction

Midazolam may be used pregnancy but risk to new-born infants should be considered when given in third trimester as there is a risk of neonatal withdrawal symptoms when used during pregnancy. Avoid regular use and use only if there is a clear indication such as seizure control. High doses administered during late pregnancy or labour may cause neonatal hypothermia, hypotonia, and respiratory depression

6. Adverse effects

The most common adverse effect is severe drowsiness (observed for several hours after administration). Approximately 12 hours is required for midazolam to be removed from the body in adults and 6 hours for children.
Full list of adverse effects listed as common (>1 in 100 to < 1in 10) are sedation, somnolence, depressed level of consciousness, respiratory depression, nausea and vomiting.
Other rare effects include agitation, restlessness and disorientation.

7. Interactions

The clinical significance of drug interactions should take into account the fact that midazolam is only used for up to 2 doses at any time.

Midazolam is metabolised by CYP3A4. Duration of action of midazolam may be prolonged by drugs which inhibit CYP3A4 including azole antifungals, macrolides antibiotics, HIV protease inhibitors , verapamil, diltiazem, St John's Wort and grapefruit juice..

The co-administration of midazolam with other sedative/hypnotic agents and CNS depressants, including alcohol, is likely to result in enhanced sedation and respiratory depression.

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

8. Monitoring

Monitor seizure activity and frequency of using buccal midazolam. Monitor liver function and adverse effects from treatment.

9. Information to patient

Patient and carer(s) should be advised that adverse effects include sedation, amnesia, impaired attention and impaired muscular function and that these effects affect the patient's ability to perform skilled tasks. After receiving midazolam, the patient should be warned not to perform skilled tasks e.g. drive a vehicle (including riding a bicycle) or operate a machine until completely recovered.

Patient and carer(s) will be provided with specific information relating to their treatment by the Epilepsy specialist nurse and/or the consultant. A manufacturer's patient information leaflet is available with the product.

10. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	-Provide test dose to evaluate for adverse event if patient has never received a benzodiazepine -Provide initial supply of midazolam. -Specific instruction for using buccal midazolam provided by the Epilepsy specialist nurse -Assess patient's response following initiation of treatment and referral from GP.	- Arrange subsequent supply via FP(10) prescription after the first treatment dose
Maintenance	- Assess clinical response to treatment - Provide adequate advice and support to GPs - Inform GP of dose amendments if appropriate	- Prescribe suggested medication - Monitor patient for efficacy and adverse effects - Refer to consultant where appropriate

Contact Details

Adults	Paediatrics
Humber Teaching NHS Foundation Trust Epilepsy Specialist Nurses- (01377) 208800 Jenny Crofts (Prescriber) Kerry Lynch **HUTH Neurology** Epilepsy Specialist Nurses- (01482) 676480/ 676438 Rebecca Bishop (Prescriber) Wendy Ainley **HUTH Neurology** Specialist pharmacist- (01482) 674411 Jane Morgan	**HUTH** Contact paediatric consultant or nurse via switchboard (01482) 875875
Out of hours: contact on call registrar for neurology via HUTH switchboard (01482) 875875	Out of hours: contact on call registrar for paediatrics via HUTH switchboard (01482) 875875

APPROVAL PROCESS

Written by:	**Jackie Stark, Medicines Management Pharmacist, HTFT**
Consultation process:	**Specialists from Paediatrics, Community Paediatrics, Neurology , Epilepsy and Learning Disabilities, HTFT DTC, LMC**
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