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 ……………………………………………………………

Specialist Prescriber’s Signature………………………………………Date:………………

GP’s Signature:………………………………………………………………………Date:………………

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 unwilling 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/content/prescribingCommittee/amber.aspx

APPROVAL PROCESS

Written by: Jackie Stark, Medicines Management Pharmacist, HFT
Updated by Marie Miller, Interface Pharmacist, Dec 2011

Consultation process: Specialists from Paediatrics, Community Paediatrics, Neurology, Epilepsy and Learning Disabilities

Approved by: HFT DTC Medicines Management Interface Group (Dec 2011)

Ratified by: HERPC January 2012

Review date: January 2014
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.

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL (91) 127 “Responsibility for prescribing between hospitals and GPs”.

2. Indication
Midazolam, a benzodiazepine 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.

The buccal liquid formulation of midazolam is now available as a licensed product, in pre-filled oral syringes.


3. Dose and administration

<table>
<thead>
<tr>
<th>Age of patient</th>
<th>Dose of buccal midazolam</th>
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</thead>
<tbody>
<tr>
<td>1 – 6 months</td>
<td>Hospital only</td>
</tr>
<tr>
<td>&gt; 6 months to &lt; 1 year</td>
<td>2.5mg in 0.5ml</td>
</tr>
<tr>
<td>1 year to &lt; 5 years</td>
<td>5mg in 1ml</td>
</tr>
<tr>
<td>5 years to &lt; 10 years</td>
<td>7.5mg in 1.5ml</td>
</tr>
<tr>
<td>10 years and above*</td>
<td>10mg in 2ml</td>
</tr>
<tr>
<td></td>
<td>May increase to 15mg (in 3ml)*</td>
</tr>
</tbody>
</table>

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 squirited into one side.

* doses above 10mg, administration of a second dose and 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 hypersensitivity to benzodiazepines, severe hepatic impairment, myasthenia gravis, severe respiratory insufficiency and sleep apnoea syndrome.
Use with caution in chronic respiratory disease; chronic renal failure, and impaired cardiac or hepatic function, patients with a history of drug or alcohol abuse.
Midazolam may be used pregnancy but risk to new-born infants should be considered when given in third trimester.

5. 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 < 1 in 10) are sedation, somnolence, depressed level of consciousness, respiratory depression, nausea and vomiting.
Other rare effects include agitation, restlessness and disorientation.

6. 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](http://www.bnf.org.uk) or SPC ([www.medicines.org.uk](http://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) 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

<table>
<thead>
<tr>
<th>Stage of Treatment</th>
<th>Hospital Specialist</th>
<th>General Practitioner</th>
</tr>
</thead>
</table>
| 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**

During office hours:

**Epilepsy Specialist Nurses**
- Karen Evans  (01482) 676480 or 676438
- Carol Ogden  (As above)
- Wendy Ainley  (As above)
- Heather Gregory (based at Four Winds, Driffield)  (01377) 208800

**Neurology specialist pharmacist**
- Jane Morgan  (01482) 674411

Out of hours: contact on call registrar for neurology via HEY switchboard (01482) 874012

**Paediatrics**

During office hours:

**Paediatric Epilepsy Nurse Specialist**
- Christine Bennett  (01482) 886518

**Paediatric Neurology Nurse Specialist**
- Nicola Heenon  (01482) 886589

**Paediatric specialist pharmacist**
- Rachel Phillips  via switchboard

Out of hours: contact on call registrar for paediatrics via HEY switchboard (01482) 875875