

SHARED CARE GUIDELINES FOR PRESCRIBING BUCCAL MIDAZOLAM (BUCCOLAM® OR EPISTATUS®) IN ADULTS

INDICATION

It is recognized that the administration of buccal midazolam for the control of prolonged, continuous or cluster of seizures is an effective treatment which can be life saving. This has resulted in its inclusion in the National Institute for Clinical Excellence (NICE) clinical practice guideline on the diagnosis and management of epilepsy in children and adults published in 2004.

The administration of buccal midazolam is considered to be a less invasive procedure than the administration of rectal diazepam and the issues of privacy and dignity are less compromised.

It should be recognized that although midazolam is a licensed drug, the use of buccal midazolam for the treatment of prolonged or continuous seizures in adults over the age of 18 is as yet, unlicensed in the UK.

For the purpose of these guidelines, the brand of buccal midazolam that should be prescribed is Epistatus® (filed for licence) or Buccolam® (licensed in under 18s) and the brand which the patient has been established on will be advised by the specialist within the care plan before transferring care.

A Specialist is defined as a Neurologist, Consultant in brain injury and rehabilitation, Consultant Psychiatrist, Paediatrician, or Epilepsy Specialist Nurse.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of buccal midazolam can be shared between the specialist and general practitioner (GP). GPs are invited to participate.

If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Specialist Responsibilities

1	To assess the patient and establish the diagnosis, determine a management strategy and ensure appropriate follow-up in conjunction with the GP.
2	To ensure the patient and carer has an individual care plan and has received training on the administration of buccal midazolam in accordance with Joint Epilepsy Council (JEC) guidelines
3	To only recommend the use of buccal midazolam when the benefits outweigh the risks. These benefits and any side effects will be discussed with the patient and the carer by the specialist
4	Once individual care plan and training are in place, to initiate treatment and provide at least 4 doses of buccal midazolam.
5	If possible, it is recommended that a test dose of midazolam is administered in hospital, particularly for patients with a medical history of respiratory problems or previous adverse reaction to benzodiazepines. If this is not possible, then it is advisable that an ambulance is called the first time midazolam is given.

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6	To provide the GP with appropriate prescribing information including background information about diagnosis, the reasons for selecting buccal midazolam, details of how to prescribe it, including details of how often doses can be repeated, maximum dose in 24 hours and details of any combination therapy and any additional information requested.
7	To be available for advice if the patient's condition changes.
8	To make every attempt to obtain consent to treatment. This includes informing the patient and carer of the medicine's license status. All information will be presented in a way that the individual can understand. The patient and carer will also be informed that the effects of an unlicensed product may be less well understood than those of a licensed product.
9	To liaise with the GP on any suggested changes in prescribed therapy.

General Practitioner Responsibilities

1	Reply to the request for shared care as soon as practicable
2	Prescribe buccal midazolam after communication with the specialist about the need for treatment
3	Refer promptly to the specialist if frequency of use increases, lack of clinical efficacy is suspected or any concerns arise
4	Report adverse events to specialist and CSM
5	Report and seek advice from specialist on any aspect of patient care that is of concern to the GP and may effect treatment
6	Stop, alter or change the treatment on advice of the specialist

Patient / Parent / carer role

1	Parents, patients and unpaid carers should attend training on epilepsy and the administration of buccal midazolam provided by The Dorset Epilepsy Service (Friends and Family session).
2	Paid staff are only permitted to administer buccal midazolam if they have Epilepsy Awareness training which is updated every 2 years and have been trained to administer buccal midazolam in accordance with JEC standards – It is the responsibility of the care provider to ensure that all staff are up to date with their training.
3	Participate in developing an individualised care plan with the specialist
4	To keep a record of when buccal midazolam is given alongside a seizure diary or equivalent
5	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
6	Attend appropriate GP and other follow up appointments
7	Share any concerns in relation to the treatment with midazolam
8	Use written and other information on the medication.
9	Seek help urgently if suspect adverse effects, or otherwise unwell.

SUPPORTING INFORMATION

Before prescribing Buccal Midazolam the patient and their family should be informed that it is an unlicensed drug and a controlled drug.

Training

Epilepsy awareness training and buccal midazolam training will be provided by an epilepsy specialist nurse. The core components for this training will meet JEC guidelines. Training is available for both unpaid and paid carers.

Organisational / care home setting

- It is the individual organisation's responsibility to produce a statement regarding liability insurance to the effect that it covers staff carrying out the procedure

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- Only people who have been trained directly by Dorset Epilepsy Service or a specialist should be asked to administer buccal midazolam. Midazolam training should not be cascaded to fellow staff
- At all times, staff and carers should be required to act within the guidelines of the individual care plan. Acting outside these guidelines carries personal responsibilities. Staff and carers will be made aware of this during training.

Individual care plan

This will include the following

- Name, Date of birth and patient number
- Possible seizure triggers
- Detailed seizure classification and description, including which seizures should be treated with buccal midazolam.
- Usual duration of seizure and normal recovery from seizure
- Contraindications (if any)
- Dose of Buccal midazolam to be given, time and by which method (buccal or in some cases, nasal)
- Usual reaction to medication
- Named person / people authorised to carry out this procedure
- **If** and when a second dose can be given (it should be noted that there is an increasing risk of respiratory depression when more than two doses of a benzodiazepine are administered). General guideline for community use is for one dose only to be given. Second dose should be administered if needed with paramedics present.
- Maximum dose in 24 hours
- When emergency assistance should be sought
- DES Adult care plans are flagged electronically to SWAST

Dosage and Administration

Most epileptic seizures stop within 5 minutes. Since midazolam causes severe drowsiness, administration should be delayed for 5 minutes to avoid giving it unnecessarily. However, if it is known that the condition always lasts for more than 5 minutes, then the specialist may advise you that midazolam should be administered immediately.

Adults:

10mg Midazolam (base) dose is considered the standard dose for adults. Epistatus is 10mg in 1ml whereas Buccolam is 10mg in 2ml. The care plan will clearly state that 10mg should be used.

Epistatus and Buccolam is designed to be given buccally (buccal applies to the area between the lower gums and inner cheek area of either side of the mouth). In a few patients, it may need to be given intranasally and this should be clarified on the individual care plan.

The first effects of midazolam should be seen after approximately 5 minutes and the condition controlled within 10 minutes. Drowsiness will be observed for several hours after administration. Midazolam should be excreted from the body of an adult in 12 hours.

Contraindications and precautions

Contraindications include hypersensitivity and acute narrow angle glaucoma. The safety of midazolam in pregnancy has not been established.

Side Effects

The most common adverse effects are severe drowsiness. However, agitation, restlessness, and disorientation have been reported, although these are rare.

Treatment of overdose

Overdoses of buccal midazolam may be manifested by one or more of the following; excessive sleepiness, confusion, low blood pressure, shallow breathing, excitation.

Overdoses can be treated with Flumazenil, which is a short-acting benzodiazepine antagonist. Flumazenil is administered as a 200 microgram intravenous bolus over 15 seconds, then 100microgram boluses at one minute intervals until the desired levels of consciousness is obtained (maximum 1mg).

The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

References

1. Epistatus® (Special Products Limited) Information. March 2006
2. Protocol for the administration of buccal midazolam (adult). University College London Hospitals NHS Foundation Trust (2008)
3. A guideline on training standards for the administration of buccal midazolam. Joint Epilepsy Council (2008)

Written By	Dorset Epilepsy Service	September 2016
Approved By	Dorset Medicines Advisory Group	September 2016

Review Date	September 2018 or before in the light of new evidence and/or recommendations
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