Oxfordshire Clinical Commissioning Group

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Oxfordshire Clinical Commissioning Group, Oxford University Hospitals NHS Trust and Oxfordshire Health NHS Foundation Trust
Shared Care Protocol and Information for GPs

Buccal Midazolam
For the treatment of prolonged epileptic seizures, clusters of epileptic seizures and status epilepticus.

This leaflet provides the necessary information and guidance for the shared care of adults & children requiring Buccal Midazolam therapy

This shared care agreement states how prescribing and monitoring responsibilities can be shared between the specialist and primary care. Shared care should only take place when all parties, including the patient, agree. A GP should only take on the prescribing if he/she has been provided with all the necessary information from the specialist and feels that it was within his/her competency to do so. APCO have agreed that if these conditions are met then this medicine is suitable for shared care under this protocol.

Summary
Benzodiazepines are established in the treatment of epilepsy. Rectal diazepam is a licensed product available for the treatment of status epilepticus, clusters of seizures and prolonged seizures. Using the rectal route can be practically difficult, socially unacceptable and have variable bio absorption. Buccal midazolam has practical advantages with regard to privacy, dignity and of ease administration. Midazolam is rapidly absorbed through the buccal cavity.

Buccal Midazolam is approved for use by the National Institute for Health and Clinical Excellence (The Diagnosis and Management of the Epilepsies in Adults and Children in Primary and Secondary Care NICE Clinical Guideline CG137, 2012)

Indications
Buccal Midazolam is indicated as an alternative or in certain circumstances as a combination therapy with rectal diazepam for individuals prone to prolonged epileptic seizures, clusters of seizures or status epilepticus.

Prescribing Information

The standard buccal midazolam dose for **adults** is 10mg.
Children's doses are as per BNFC;

3 months to 1 year	2.5mg
1 to 5 years	5mg
5 to 10 years	7.5mg
10-18 years	10mg

All can be repeated ***ONCE*** after 10 minutes if necessary

Ensure that the correct formulation is prescribed.

- Buccal midazolam should always be prescribed by brand
- The dose should always be prescribed in mg and in ml
- Avoid switching preparations unless advised to do so by the secondary care team.

Written by <*Dr Jane Adcock*> (Consultant), Maggie Tristram (Specialist Nurse) and Olivia Moswela (Clinical Pharmacist)
Version ?: Approved by Area Prescribing Committee for Oxfordshire (APCO)… <*Insert date*> Review Date: …<*Insert date*>

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Buccal midazolam is available as:

Buccolam® a preparation of buccal Midazolam Hydrochloride 5mg/ml is licensed for paediatric use (age 3 months to 18 years). Buccolam® is available in a range of prefilled syringes of 2.5mg in 0.5ml, 5mg in 1ml, 7.5mg in 1.5ml and 10mg in 2ml.

Epistatus® is an unlicensed preparation of buccal Midazolam Maleate (available on a name patient basis from Special Products Limited). Epistatus® is a sweetened, sugar free midazolam 10mg/ml formulation available as:

1. Epistatus® 10mg/ml solution in 5ml bottles along with 4 x 1ml empty oral syringes and instructions for use.

2. Epistatus® 10mg/ml solution in prefilled 2 syringe packs of 2.5mg(in 0.25ml), 5mg(in 0.5ml), 7.5mg(in 7.5ml) and10mg(in 1ml) strengths.

In addition to the above two brands, there are a number of further products now available with different presentation and instructions for administration which can lead to confusion for patients and carers

How to administer buccal midazolam

The full dose should be drawn up into an oral syringe (or a Prefilled Syringe is used) and approximately half the amount dripped into the spaces between the lower gums and the cheek on one side of the mouth. The remaining liquid should be dripped between the lower gums and cheek on the other side of the mouth. If necessary, the whole dose can be given just on one side of the mouth.
There is a continuing care-shared care protocol for the training of carers to administer buccal midazolam.

Adverse Effects

The most common reported side effect is drowsiness; in some cases this may be severe. All patients receiving midazolam are likely to be drowsy for several hours after administration.
Agitation, restlessness and disorientation have been reported, although these are rare. As for any medicine, all suspected adverse reaction should be reported to the CSM.

Contra-indications/Cautions

- Buccal midazolam is contraindicated in hypersensitivity to midazolam, benzodiazepines, or to any of the excipients.
- Midazolam should be used with caution in patients with chronic respiratory insufficiency because it may further depress respiration.
- Midazolam may accumulate in patients with chronic renal failure, or impaired hepatic or cardiac function and should therefore be used with caution in these individuals.

Pregnancy

- Safety has not been established.

Lactation

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- Midazolam passes in low quantities (0.6%) into breast milk.

Drug Interactions
Midazolam is metabolized by CYP3A4. Inhibitors and inducers of CYP3A4 have the potential to respectively increase and decrease the plasma concentrations and, subsequently, the effects of midazolam thus requiring dose adjustments accordingly. Refer to BNF and buccolam SPC for a list of interacting drugs

Monitoring
- No specific monitoring is necessary

Patient Information Leaflet
Patients should be supplied with an information leaflet from the manufacturer and/or the hospital team.

Shared Care Responsibilities
Shared care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them. Patients should be under regular follow-up which provides an opportunity to discuss drug therapy.

Aspects of care for which the Hospital Consultant is responsible:
Advise GP of recommendation to initiate treatment. The specialist must make every attempt to obtain consent to treatment.

Use licensed preparations in preference to those which are unlicensed. Initiate or switch to the Buccolam preparation as appropriate. Consider the use of unlicensed medicines and only recommend use when the benefits outweigh the risks. These benefits and any side effects should be discussed with the patient and the carer.

The patient and carer must be informed of the medicine's licence status and the implications of its use. All information should be presented in a way that the individual can understand.

Ensure the patient and their carer understands when and how to give the medication. (An identified member of the specialist team, such as the epilepsy specialist nurse or where appropriate the learning disabilities nurse or disability support nurse will work with the patient and carer to develop a protocol for administration, train in use, ensure appropriate storage and provide written/verbal advice in an appropriate format.

Write to the GP requesting shared care and outline shared care protocol criteria.

The GP must be informed of the medicine's licence status when asking them to use unlicensed medicines.

Supply GP with background information about diagnosis, the reasons for selecting midazolam and 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. This summary should be received within 14 days of a hospital outpatient review or in-patient stay.
Review the patient's condition and monitor response to treatment regularly (at least 6 monthly).

Liaise with GP regarding changes in disease management, drug dose, and missed clinic appointments.

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Advise GP on when to stop, alter or change treatment, in particular when switching from an unlicensed buccal midazolam product to a licensed one.

Provide clear instruction to GP on when therapy needs to be referred back to specialist.

Ensure the patient understands the nature and complications of drug therapy and their role in reporting adverse effects promptly.

Report adverse events to the CSM

Ensure clear arrangements for GP and carer back-up, advice and support.

Aspects of care for which the GP is responsible:
Reply to the request for shared care as soon as practicable

Prescribe branded midazolam after communication with specialist about need for treatment, ensuring the correct formulation is prescribed. *NB GP should not switch formulations as this has implications for the ability of paid carers to administer the buccal midazolam.*

Refer promptly to specialist if frequency of use increases, lack of clinical efficacy is suspected or any concerns arise.

Report to and seek advice from specialist on any aspect of patient care that is of concern to the GP and may affect treatment

Advise the Hospital Consultant of any clinical changes where appropriate.

Report adverse events to specialist and MHRA

Stop, alter or change the treatment on advice of the specialist.

Aspects of care for which the Patient is responsible:
Report any adverse effects to their GP and/or consultant

Share any concerns in relation to treatment with buccal midazolam

Report to the specialist or GP if they do not have a clear understanding of their treatment.

Attend for regular monitoring as outlined in patient information leaflet.

Back up advice and support
Paid carers should receive training in supporting individuals with epilepsy and the administration of buccal midazolam as per guidelines published by the Joint Epilepsy Council (October 2005) or the shared care protocol for the administration of Buccal Midazolam (once ratified)

In care home settings a formal record should be kept detailing the patient's identity, name and dose of medication prescribed and a clear description of when it should be administered.

Contact Details

Dr Jane Adcock

Oxfordshire Clinical Commissioning Group

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Department of Neurology
Telephone 01865 231891

Maggie Tristram
Epilepsy Specialist Nurse
Telephone: 01865234222

John Radcliffe Hospital
Neurosciences- West Wing
Headley Way
Headington
Oxford OX3 9DU

Learning Disability Nurse or Disability Support Nurse:

Supporting information:

National Institute for Clinical Excellence (2012). The epilepsies: diagnosis and management of the epilepsies in adults in primary and secondary care. London. NICE. Available online from the NICE website http://guidance.nice.org.uk/CG137

Prevention of Harm with Buccal Midazolam | Signal NPSA Feb 2012
http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=132975

Buccal midazolam (Buccolam▼): new authorised medicine for paediatric use—care needed when transferring from unlicensed formulations. Drug Safety Update 2011; 5 (3).
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131931

Summary of Product Characteristics Buccolam® Midazolam oromucosal solution; Available at http://www.medicines.org.uk/emc/medicine/25541/SPC

Patient Information- Epistatus® Midazolam buccal liquid 10mg/ml. Special Products Limited.