

MERSEY CARE NHS TRUST – HOW WE MANAGE MEDICINES

**MM 20 ADMINISTRATION OF BUCCAL MIDAZOLAM FOR
STATUS EPILEPTICUS**

Medicines Management Services aim to ensure that
(i) Service users receive their medicines at times that they need them and
in a safe way.
(ii) Information on medicines is available to staff, service users and their
carers

KEY ISSUES

**Procedure to ensure the safe and effective administration of buccal midazolam
when prescribed for status epilepticus.**

Medicines Management Procedure – MM20
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For Review: January 2018 this procedure
replaces Calderstones Procedure No. M9.4
dated 01.06.14

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REFERENCES

Procedure 20.13 Mental Capacity Act 2005

Procedure M2.4 Use of Unlicensed Medicine

Procedure 3.0 Administration of Medicines

Procedure 24.5 Management of Epilepsy and Status Epilepticus 2005

NICE Guidelines the Epilepsies 2012

Special Projects Limited 2006

JEC A Guideline on Training Standards for the Administration of Buccal Midazolam 2012

SUMMARY OF AMENDMENTS

References

Title of Procedure amended to Administration of Buccal Midazolam for Status Epilepticus

Section 2 – Status Epilepticus

Section 3 – Midazolam – Rational Statement on Buccal Midazolam for Prescribing

Legal Category

Section 4.1, 4.2, 4.3

Treatment and Care Plan

Section 6.1, 6.3

Administration

Section 7.2

Training

Section 8.2, 8.3.2

Section 9 - Guidelines on Trainer Competency

Appendix A – Guidelines for Administration

**SUBJECT: Administration of Buccal Midazolam for Status Epilepticus
(Forensic and High Support Services)**

1. PURPOSE

This procedure will inform all direct care staff and prescribing Clinicians of the Trust's expectations in relation to the prescribing and use of Midazolam for the treatment of status epilepticus. It should be read in conjunction with Procedure 24.5 Management of Epilepsy and Status Epilepticus and Procedure M2.4 Use of Unlicensed Medicines.

2. STATUS EPILEPTICUS

In the past, status epilepticus (SE) was defined as a seizure lasting longer than 30 minutes or two or more seizures within 30 minutes without a return to the baseline level of consciousness between seizures. More recently, the definition evolved to be a seizure longer than 5 minutes or 2 or more seizures without a return of consciousness between seizures. Serial seizures are defined as 3 or more tonic clonic seizures in an hour (*National Institute for Health and Care Excellence CG137 2012*).

1. MIDAZOLAM – RATIONAL STATEMENT ON BUCCAL MIDAZOLAM FOR PRESCRIBING

It is recognised that the administration of Buccal Midazolam for the control of prolonged seizures is an effective treatment which can be lifesaving. Given promptly, this relatively simple procedure can prevent the major disruption to daily life resulting from Hospital admission (*JEC 2012*).

However, it should be recognised that although Midazolam is a licenced drug and there is now a Buccal Midazolam product licensed for the treatment of prolonged acute seizure in children and young people up to the age of 18, its use in adults is as yet unlicensed (*JEC 2012*).

The administration of Buccal Midazolam is considered to be a less invasive procedure than the administration of rectal diazepam. The issues of privacy and dignity are less compromised and in situations where it is an effective alternative. However, adults with a history of prolonged or continuous seizures should be prescribed either Buccal Midazolam **or** Rectal Diazepam. They are **not** interchangeable (*JEC 2012*).

4. LEGAL CATEGORY

4.1 Midazolam whilst a schedule 3 controlled drug (CD) does not need CD storage at ward level, however, it is good practice that when out in the community the medication is always kept on the escorting member of staff. To ensure this happens Buccal Midazolam must be carried in a bag attached to the escorting staff's body.

4.2 Midazolam Buccal Liquid is now a licensed medicine for children but being used in this situation for adults and is therefore being used for an 'unlicensed

indication' or 'off label' within the meaning of current legislation governed by the UK Medicine Acts and EU Pharmaceutical Directives.

- 4.3 When prescribing a medicine for an unlicensed indication the prescribing Clinician must be able to justify this action in accordance with a respectable, responsible body of professional opinion.
- 4.4 Calderstones Partnership NHS Foundation Trust holds public liability insurance to ensure the safety of the person carrying out administration of Buccal Midazolam and a protocol for the use of 'unlicensed medicine' (*Procedure M.24 Use of Unlicensed Medicine*).
- 4.5 The prescribing Clinician will be required to follow Procedure M2.4 Use of Unlicensed Medicines, along with any relevant national guidance and complete all relevant documentation.

5. PRESCRIBING

- 5.1 Buccal Midazolam must be prescribed by a Medical Practitioner after discussion with the service user/patient and consent being agreed.
- 5.2 For service users/patients lacking capacity a consultation should be held with the family, where appropriate and a decision regarding treatment should be made in the service user's/patient's best interest. This should be consistent with the requirements of the Mental Capacity Act 2005 (*Procedure 20.13*).

6. TREATMENT AND CARE PLAN

- 6.1 All service users/patients diagnosed with epilepsy will have a Treatment and Care Plan (*which can be found on G:\(Common Tools)\CareNotes\Templates*) in place that incorporates guidance laid out by NICE (CG137) and Procedure 24.5 Management of Epilepsy and Status Epilepticus. Directions for the administration and use of Buccal Midazolam will be laid out within this Treatment and Care Plan.
- 6.2 All staff required to administer Buccal Midazolam will be trained in its administration and record of this training will be kept within the Learning and Development Centre.
- 6.3 Support Workers/unregistered staff will be trained in the administration of Buccal Midazolam.
- 6.4 The Nurse in Charge will ensure a copy of the Treatment and Care Plan along with prescribed medication is carried by the authorised escort for all off site outings.

7. ADMINISTRATION

Most (75%) epileptic seizures stop within 5 minutes. Since Buccal Midazolam may cause severe drowsiness, it should not normally be administered until after the seizure has lasted 5 minutes. Most (80%) seizures are terminated within 10 minutes of Buccal administration of Midazolam (Special Products 2006).

- 7.1 First dose of Midazolam to be administered as per individual emergency guidelines (*Treatment and Care Plan, Care Notes*).
- If no effect is apparent 10 minutes after administering Midazolam (*and breathing remains normal*) then administer another dose.
 - If no effect apparent 5 minutes after administering the second dose of Midazolam, then call an Ambulance.
- 7.2 Side effects can include Paradoxical reactions, e.g. agitation, restlessness and disorientation. Respiratory depression needs close observation and monitoring. The person may also show signs of memory loss. Grapefruit juice must be avoided as this can interfere in the absorption of Midazolam and actually increase the sedative effects of the medication.
- 7.3 Where a second dose may be required this will be identified within the individuals Treatment and Care Plan, the dose must be prescribed by a Clinician.
- 7.4 All administrations of Buccal Midazolam must be documented within the service user's/patient's CareNotes and Medicine Card.
- 7.5 Appendix A provides further guidance on the administration of Buccal Midazolam.

8. TRAINING

- 8.1 It is the Ward Manager's responsibility to ensure that named individuals are adequately trained and up to date in the administration of Buccal Midazolam. All staff working with an individual prescribed Buccal Midazolam must attend epilepsy awareness and administration of Buccal Midazolam training and receive a certificate of attendance. A refresher must be attended within 2 years.

The Trust's Learning and Development Centre will take responsibility for the delivery of Buccal Midazolam administration training and maintaining a record of all staff attendance.

8.2 Core Components of a Buccal Midazolam Training Course (JEC 2012)

- Epilepsy Awareness
- The Administration of Buccal Midazolam
- Health and Safety Issues
- Opportunity for Discussion

It is recommended that a minimum of 2-3 hours education (*dependant on group size*) is required to cover all the components.

Epilepsy Awareness

- What is epilepsy?

- Causes.
- How a diagnosis is made.
- Types of seizures (*with reference to current classification of the International League Against Epilepsy*).
- Treatment with antiepileptic medication and side effects.
- First aid.
- Status Epilepticus.
- Psychosocial issues for people with epilepsy, including cultural issues.
- Sources of information and support for people with epilepsy, their families and carers.

The Administration of Buccal Midazolam

- What Midazolam is.
- Its uses for epilepsy and other conditions.
- Indications for the use of Midazolam.
- Different routes of delivery and appropriate doses when given buccally.
- The benefits of Buccal Midazolam.
- Practical demonstration using video and/or volunteer.
- Possible difficulties in administrations (*e.g. excessive salivation, injury to mouth etc*).
- Consequences of too much Midazolam being given and how this can be identified.
- Appropriate action to be planned in case of an overdose.
- Action if Midazolam is ineffective.

Health and Safety Issues

- Risk Assessment.
- The Individual Care Plan
- Secure storage and safe disposal.
- Duty of care issues.
- Legal responsibilities of teachers, carers, etc.

- Awareness of local policies on the administration of Buccal Midazolam.

8.3 Assessment of Learning

8.3.1 There are recognised difficulties associated with assessing the knowledge and skills of participants who undergo training in the administration of Buccal Midazolam. Most training providers will be unable to assess participants as they carry out this procedure in their day to day work, as this is a procedure used in an emergency which cannot be predicted.

8.3.2 An employer organisation should consider assessment important and good practice recommends the following options are fulfilled as far as possible:-

- During the course a training provider checks that learning is taking place, supervising the participant in a simulated procedure, using a volunteer with water as the medication.
- It is recommended a certificate of attendance will be issued when the trainer is fully satisfied that learning has taken place.
- Following the course a training provider or work based assessor assesses the participant using the following:-
 - Questioning, oral or written.
 - Case studies.

8.4 Retraining

It is recognised that the administration of Buccal Midazolam is an emergency treatment and may not be used on a regular basis, how often people use the procedure will affect their skills and it is recommended that named individuals attend a refresher course at intervals of not more than 2 years.

9. GUIDELINES ON TRAINER COMPETENCY

- Will be suitably trained in administering Buccal Midazolam, with relevant practical experience.
- Have a minimum of 1 year's experience in delivering training/facilitation courses to adult students or evidence of teaching skills. Suggested qualifications: ENB 998: Teaching and Assessing in Clinical Practice, City and Guilds 7303/4/5, PGCE or any other relevant adult teaching certificate.
- Can demonstrate that they keep their knowledge and experience up to date by attending training courses, seminars and conferences on epilepsy as appropriate, and at least annually.
- Trainers have a responsibility to provide accurate up to date information and to teach a procedure which is generally as good practice (*JEC 2012*).

GUIDELINES FOR ADMINISTRATION

Equipment Needed

Midazolam as prescribed

Seizure description/emergency guidelines

Pre-filled syringe

Procedure for Administration

- Check medication card prescription current and in date with witness.
- With a witness check dose, expiry date of Midazolam and that the liquid is clear (*do not use liquid that is milky or has particles in it*).
- Carefully remove syringe cap
- If possible turn the person on their side.
- Using the index finger, as this has less power than the thumb, and also ensures that the syringe is at the correct angle to administer the Midazolam, slowly squirt about half the prescribed dose between the lower gum and cheek on one side of the mouth.
- Put the remaining liquid between the lower gum and cheek on the other side of the mouth.
- If administration is difficult squirt the whole dose into one side only.
- Record dose and time given on medicine card and epilepsy record in EPR.
- Remain with the person until fully recovered.
- Observe breathing and colour, Midazolam can make breathing shallow.
- If difficulty in giving Midazolam or concern following administration discuss and review emergency guidelines.