



Family Nursing & Home Care

Guidelines and Standing Operating Procedures

Administration of Buccal Midazolam to adults who have prolonged epilepsy seizures

2015

Type i.e. Strategy, Policy, Education Package etc.	Guideline and Standard Operating Procedures
Name	Administration of Buccal Midazolam to Adults who have Prolonged Epilepsy Seizures
Category i.e. organisational, clinical, Corporate, Finance etc	Clinical
Version	1
Author	Working Party Lead: Elspeth Snowie (Clinical Effectiveness Facilitator)
Approved by i.e. Operational Governance Group	Chief Executive Officer – Julie Gafoor
Date Approved	11/08/15
Review Date	11/08/18
Person responsible for review	Clinical Effectiveness Facilitator
Approved by i.e. Sub Committee, H&SS	

This document supersedes the document 'Policy and Procedure for the administration of Buccal Midazolam Liquid for Named Children by Qualified Nurses and Named Teachers/Support Workers at Mont a L'Abbe School'

This guideline and Standard Operating Procedures have been adapted for local use from the Berkshire Healthcare NHS Foundation Trust's 2013 guidelines 'Buccal Midazolam (Administration of Buccal Midazolam for Adults and Children who have Prolonged Epilepsy Seizures)

Index

Content	Page
1. Introduction	1
1.1 Rationale	1
1.2 Scope	1
1.3 Principles	1
2. Guidance	1
2.1 Licensed Indication/Use	1
2.2 Buccal Midazolam Presentations	2
2.3 Training	2
2.4 Multi Agency Working	2
2.5 Authorisation to Administer Buccal Midazolam	2
2.6 Supply of Buccal Midazolam	2
2.7 Storage of Buccal Midazolam	2
2.8 Administration of Buccal Midazolam Preparations	3
2.9 Supporting the Carer to Administer Buccal Midazolam	3
2.10 Disposal of Buccal Midazolam	3
2.11 Reporting Adverse Reactions	3
3. Standard Operating Procedures	
3.1 Administration of Buccal Midazolam from a pre-filled Oral Syringe	5
3.2 Administration of Buccal Midazolam Supplied in a Bottle with non-prefilled oral syringes e.g.	6
3.3 Care of the patient following administration of buccal midazolam	7
4. Quality Standards	8
5 Development and Consultation	8
5.1 Consultation Schedule	8
6 References	9
7 Bibliography	10
8 Appendices	
1. Individual Health Care Plan for the Management of Prolonged Seizures	
2. Competence in Clinical Skills	

1. Introduction

1.1 Rationale

This clinical guideline and standard operating procedures (SOPs) have been developed to enable nurses and trained healthcare professionals to administer buccal midazolam preparations for the emergency treatment of adults with prolonged epilepsy seizures. It also provides guidance for nurses to train others on the correct administration of the buccal midazolam preparations available as outlined.

Midazolam is a short-acting benzodiazepine which can be administered via the oral, buccal, rectal, intravenous and intramuscular routes.

Midazolam administered by the buccal route is indicated for the emergency treatment of status epilepticus and is the first line treatment in adults with prolonged or repeated seizures in a community setting (NICE 2012). NICE (2014) define “prolonged” as lasting five minutes or more and “repeated” as three or more seizures in an hour.

Midazolam is classified as a Schedule 3 Controlled Drug (CD) and its use is governed by the Misuse of Drugs (Jersey) Law 1978 & Customs and Excise (Jersey) Law 1999. It is exempt from storage and recording regulations.

Currently in Jersey, buccal midazolam is not available on the GP prescribing list and can therefore only be prescribed by a hospital doctor.

1.2 Scope

This document is applicable to:

- FNHC staff who administer buccal midazolam as indicated for the emergency treatment of prolonged epilepsy seizures
- FNHC staff who provide training to non-FNHC staff for the administration of buccal midazolam in the community.

This clinical guideline and SOPs outline the prescribing, supply, storage and administration of buccal midazolam. The administration of buccal midazolam should be undertaken in accordance with this document and the FNHC Medicines Policy.

The term buccal midazolam will be used throughout this document to mean all the different buccal midazolam preparations available. Buccal midazolam is also known as midazolam oromucosal solution.

1.3 Principles

Family Nursing and Home Care believes that all patients should receive the same standard of care regardless of who is administering the buccal midazolam.

Care should be based on current best practice and patient safety should be maintained at all times.

2. Guidance

2.1 Licensed Indication/Use

Buccolam® is the first buccal midazolam licensed product. It has a paediatric licence to treat prolonged, acute convulsive seizures from the ages from 3 months up to and including 17 years. This is usually the preparation of choice used locally.

Use of the licensed preparation Buccolam® for individuals 18 years and over is an “off label/off licence” use for the product and is outside of the recommendations of the marketing authorisation. This “off licence” use is justified in the emergency situation outlined in this guideline and SOPs.

Buccal midazolam prescribed by a doctor for the emergency treatment of prolonged epilepsy seizures may be administered by FNHC staff. Use in these circumstances

will be supported by FNHC if done in accordance with this guideline and SOPs and in accordance with the FNHC Medicines Policy.

2.2 Buccal Midazolam Presentations

Buccal midazolam is supplied in two different preparations. It can come as a single dose prefilled oral syringe as Buccolam® in an age-specific, pre-filled needle-free oral syringe. Each syringe is colour coded and contains the prescribed dose for a particular age range. There are four strengths available (ViroPharma 2014). Buccal Midazolam also comes in a bottle with non-prefilled oral syringes e.g. Epistatis®. In 2012 an NPSA alert highlighted dosing and administration errors as a result of the wrong type of syringe used (MHRA, 2012, Patient Safety, 2012). To minimise the risk, Buccolam® is usually the preparation of choice locally.

2.3 Training

All staff required to administer buccal midazolam or teach others how to do this must have successfully completed training in this technique.

Individuals administering buccal midazolam and/or providing training in the administration of buccal midazolam should keep their knowledge and skills updated.

2.4 Multi-Agency Working

Where Family Nursing and Home Care (FNHC) staff are working in collaboration with other agencies e.g. Jersey Hospice Care, use of the 'Individual Health Care Plan for the Management of Prolonged Seizures' (Appendix 1) should be encouraged. Completion of this care plan should be in collaboration with the prescribing medical practitioner as well as with the patient and other relevant parties involved in the patient's care.

2.5 Authorisation to Administer Buccal Midazolam

The administration of buccal midazolam for an emergency situation must be authorised by a Registered Prescriber on either the 'Individual Health Care Plan for the Management of Prolonged Seizures' (Appendix 1) or in the patient's nursing record.

2.7 Supply of Buccal Midazolam

The patient will have their own buccal midazolam (prescribed by a Hospital Doctor). This product must contain a Pharmacy dispensed label with the patient's name and clear directions for use.

2.8 Storage of Buccal Midazolam

Midazolam has the potential to be misused, therefore, storage arrangements must ensure that the products are securely stored but accessible to those who are authorised to administer the medicine. Whilst FNHC is not usually responsible for the storage of midazolam, staff should advise those who are of the correct arrangements.

Buccal midazolam should be stored in accordance with the manufacturer's information:

- Buccal midazolam unlicensed preparations stored in a bottle should be kept at room temperature. The cap must be replaced immediately after use otherwise the liquid will evaporate and some of the midazolam will precipitate. This will be exhibited as white particles in the liquid. The pack must be discarded if the solution is not clear.
- Syringes of Buccolam® must be kept in the protective plastic tube until used. The product should not be refrigerated or frozen.

2.9 Administration of Buccal Midazolam Preparations

The following FNHC staff can administer buccal midazolam:

- Registered nurses
- Other FNHC staff trained in the administration of buccal midazolam and the administration has been delegated by a registered nurse. They must have been deemed competent as having successfully completed all necessary training.

Those administering the buccal midazolam must ensure that the medication, prepared and administered as rescue medication, follows the principles of safe preparation.

The correct administration technique should be followed for the different presentations in which buccal midazolam may be prescribed. Family Nursing and Home Care has standard operating procedures for administering buccal midazolam supplied in a pre-filled syringe and in a bottle with non-pre-filled syringes (Appendix 2)

2.10 Supporting the Family/Carer to Administer Buccal Midazolam

There may be times when it is appropriate for the registered nurse to train the patient's family/carers in the administration of buccal midazolam.

When the administration of buccal midazolam is a delegated task, the delegatee must be deemed competent by the Registered Nurse on the appropriate FNHC documentation (Appendix 2). The Registered Nurse should also ensure the 'Individual Health Care Plan for the Treatment of Prolonged Seizures' is completed and is discussed with and understood by the family/carers.

Training for family/carers on the administration of buccal midazolam should include (but is not limited to):

- information about the medication including safe storage arrangements
- administration of buccal midazolam and care following administration (see SOPs in section 3 above)
- the necessary documentation that needs to be completed

2.11 Disposal of Buccal Midazolam

The healthcare professional should advise the individual/family/carers to return expired midazolam to a community pharmacy for safe disposal.

2.12 Reporting Adverse Drug Reactions (ADR)

In the event of an adverse reaction, immediate action should be taken to minimise the harm to the patient. Inform the prescribing medical practitioner and GP of the actions taken and record in the patient's notes. Any ADR should be reported in accordance with FNHC's Incident Reporting Policy. Any ADR should also be reported to the Medicines & Healthcare Products Regulatory Agency (MHRA) by completing an adverse drug reporting form ('Yellow Card').

Administration of Buccal Midazolam from a Pre-filled Oral Syringe

Purpose

To support the safe administration of buccal midazolam supplied in a pre-filled syringe e.g. Buccolam®

Scope

This SOP pertains to buccal midazolam supplied in a pre-filled syringe for use in the emergency treatment of prolonged seizures (status epilepticus). It covers pre-administration checks and administration technique

Core Requirements

The principles of safe administration of medicines including the recording of the administration must be followed as per the most up to date version of the Nursing and Midwifery Council's Standards for Medication Administration and local Medicines Policy.

How to administer Buccolam® (pre filled oral syringe)

- Before use, always check the expiry date stated on the carton, tube and syringe labels. Buccolam® should not be used if any of the protective plastic tubes containing the syringes have been opened or are damaged.
- Take one plastic tube, break the tamper proof seal and remove the syringe containing Buccolam®
- Remove and discard the red syringe cap before use to avoid choking. Do not put a needle on the syringe. Each syringe is pre-filled with the dose prescribed to be given for one treatment.
- To administer Buccolam®, cushion the patient's head with something soft. If the patient is seated, you may find it easier to support their head against your body, leaving your hands free to administer Buccolam®.
- Gently pull back the patient's cheek, just enough to put the end of the syringe into the side of their mouth, between the gum and the cheek (buccal cavity).
- Angle the syringe to ensure that the end is well within the buccal cavity.
- Slowly press the syringe plunger to release the full amount of Buccolam® into the side of the mouth. Do not try to squirt the liquid into the mouth or release it too quickly as this may result in spillage. It may be easier to give about half the Buccolam® dose into one side of the mouth and the other half into the other side.

3. Standard Operating Procedures

Administration of Buccal Midazolam Supplied in a Bottle with Non Pre-filled Oral Syringes e.g. Epistatis®

Purpose

To support the safe administration of buccal midazolam supplied in a bottle with non-pre-filled syringes e.g. Epistatis®

Scope

This SOP pertains to buccal midazolam supplied in a bottle with non-pre-filled syringes for use in the emergency treatment of prolonged seizures (status epilepticus).

Core Requirements

The principles of safe administration of medicines and the recording of the administration must be followed as per the most up to date version of the Nursing and Midwifery Council's Standards for Medication Administration and local Medicines Policy.

Drawing up and administering a dose of buccal midazolam (in non-prefilled syringe)

- Check the dosage of the buccal midazolam is correct for the individual and the medication is in date.
- Check the oral dispenser is a 1ml oral dispenser.
- Put on gloves.
- Hold the bottle upright.
- Remove the child resistant cap by pushing it down and turning it anti clockwise.
- Push the 1ml oral dispenser (syringe) completely down towards its tip.
- Insert the tip of the oral dispenser into the hole in the white plastic bottle adaptor. Hold the bottle and the oral dispenser securely and turn the bottle up-side-down.
- Pull the plunger out slowly until the oral dispenser contains the prescribed amount of liquid for the person (as per written instruction by the authorised prescriber).
- Turn the bottle upright.
- Remove the oral dispenser from the bottle.
- Support the person's head and chin.
- Put about half of the liquid in the oral dispenser between the patient's lower gums and cheek (buccal cavity). Do not administer the dose below the tongue since the teeth may clamp and break the syringe in the mouth. Do not let the patient bite the oral dispenser.
- Be careful that you do not press the plunger when you remove it as this will mean that you do not have the complete dose.
- Put the remaining liquid between the lower gums and cheek on the other side of the mouth.
- Support the cheeks/lips whilst giving the buccal midazolam and afterwards to reduce the amount of leakage.
- Put the cap back onto the bottle.
- Put the bottle back in the carton containing the remaining oral dispensers.

Care of the patient following administration of buccal midazolam

Purpose

To support the safe aftercare of a patient following the administration of buccal midazolam for the emergency treatment of a prolonged seizure.

Scope

This SOP applies to all FNHC staff following the administration of buccal midazolam for the emergency treatment of prolonged seizures.

Core Requirements

After the administration of buccal midazolam:

- Stay with the patient after administration. Maintain close observation and monitor their condition and breathing. As the seizure subsides, check airway and breathing. If breathing, put into the recovery position until he/she recovers consciousness. If not breathing commence CPR.
- The initial effect of the midazolam should be apparent after approximately five minutes.
- Check that the symptoms of the seizure are subsiding/stopping after you give the buccal midazolam. If there is no change in the person's condition within approximately five minutes, then telephone for an ambulance immediately or follow the patient's care plan.
- Once the patient has recovered, write down the date, time and route of giving the buccal midazolam and sign that they have given this in the patient's records.
- Ensure that all used equipment and bottles of medicines are disposed of safely.
- Relatives/carers should also be informed at the earliest opportunity that buccal midazolam has been administered. It is important that this information is recorded in writing on the relevant documentation.
- The frequency of administration should be brought to the attention of the prescribing clinician.
- Re-order Buccal Midazolam to maintain adequate stock.

4. Quality Standards

This guideline and standard operating procedures (SOPs) link to the following Quality Assurance Framework (QAF) quality standards:

1. Care and welfare of people who use services
3. Management of Medicines
5. Respecting and Involving People who use the Services
8. Cooperating with Other providers
14. Consent to Care and Treatment
15. Records
16. Supporting workers

5. Development and Consultation

5.1 Consultation Schedule

The following staff were consulted during the development of these guidelines and SOPs

Name	Title
Jane Le Ruez-Lane	Patient Safety Facilitator
Lindy Henesy	Team Leader Children's Community Nursing Team
Julia Foley	District Nurse – Town Team
Jo Davies	Team Leader School Nursing team
Clare Stewart	Acting Operational Lead for Rapid Response & Re-ablement
Grade 6 and 5 District Nurses	
Phil Romeril	Pharmacist

This document has been reviewed by the following groups

Name of Committee/Group	Date of Committee/Group
Policy and Procedures group	2 nd June 2015
Operational Governance group	16 th July 2015

6. References

Berkshire Healthcare NHS Foundation Trust (2013) Buccal Midazolam (Administration of Buccal Midazolam for Adults and Children who have Prolonged Epilepsy Seizures), http://berkshirehealthcare.nhs.uk/_store/documents/buccal_midazolam_guidelines.pdf (last accessed 6.11.14)

British Medical Association and the Royal Pharmaceutical Society (2012) Midazolam, *British National Formulary*, 15.1.4.1, Pharmaceutical press, Basingstoke.

Medicines and Healthcare Products Regulatory Agency (2012) Class 4 Drug Alert: Epistatus, Midazolam 10mg in 1ml Buccal Liquid x 5ml (M11) - EL(12)A/08, <http://www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON143794> (last accessed 10.11.14)

NICE (2014) NICE Pathway, Treating Prolonged or Repeated Seizures and Convulsive Status Epilepticus, <http://pathways.nice.org.uk/pathways/epilepsy> (last accessed 6.11.14)

NICE (2012) NICE Guidelines CG137 The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care, last modified December 2013, <http://www.nice.org.uk/guidance/cg137/resources/guidance-the-epilepsies-the-diagnosis-and-management-of-the-epilepsies-in-adults-and-children-in-primary-and-secondary-care-pdf> (last accessed 10.11.14)

Patient Safety (2012) Prevention of Harm with Buccal Midazolam, Signal, <http://www.nrls.npsa.nhs.uk/resources/?entryid45=132975> (last accessed 10.11.14)

Penn Specials (2010) Technical Information Leaflet for Penn Midazolam. Midazolam Buccal Liquid 10mg/ml, www.pennpharm.com

Specials Products Ltd (2012) Data Sheet for Epistatus, Version 9 27/7/2012

ViroPharma (2014) Buccolam® Summary of Product Characteristics, <https://www.medicines.org.uk/emc/medicine/25538> (last accessed 10.11.14)

ViroPharma (date unknown) "How to administer BUCCOLAM® (midazolam oromucosal solution)" <http://uk-buccolam.north51digital.com/hcp/dosing-and-administration/Administration> (last accessed 10.11.14)

7. Bibliography

Medicines and Healthcare Products Regulatory Agency (2011) Buccal midazolam (Buccolam ▼): new authorised medicine for paediatric use—care needed when transferring from unlicensed formulations, <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131931>

NICE (2013) Quality Standard for the Epilepsies in Adults, QS 26, <http://www.nice.org.uk/guidance/qs26> (last accessed 10.11.14)

NICE (2013) Quality Standard for the Epilepsies in Children and Young People, QS 27, <http://www.nice.org.uk/guidance/qs27> (last accessed 10.11.14)

Individual Health Care Plan for the Management of Prolonged Seizures

Individual Health Care Plan to be completed by or in consultation with the prescribing Medical Practitioner (Please use language appropriate to the lay person)

Name:		Attach photographic identification
GP:		Consultant:
Tel:		Tel:
Date of Birth	Sex: Male/Female	Prescribing Weight (children only)
Date:		
<p>Seizure classification and/or description of seizures which may require buccal midazolam (Record all details of seizures e.g. goes stiff, falls, convulses down both sides of body, convulsions last 3 minutes etc. Include information regarding triggers, recovery time etc)</p> <p>1. Usual duration of seizure</p> <p>2. Usual duration of seizure</p> <p>3. Usual duration of seizure</p> <p>Other useful information</p> <p>.....</p>		

Midazolam Treatment Plan for:

1.	When should buccal midazolam be administered? (Note here should include whether it is after a certain length of time or number of seizures)
2.	Dosage: How much buccal midazolam is to be given? (Note recommended number of milligrams for this person)
3.	What is/are the usual reaction(s) to buccal midazolam?
4.	If there are difficulties in the administration of buccal midazolam what action should be taken?
5.	ONLY ONE dose of buccal midazolam must be given
6.	Dial 999 for emergency services on administration of buccal midazolam
7.	Who should witness the administration of buccal midazolam?
8.	Who needs to be informed? Prescribing doctor for re-ordering of buccal midazolam TEL: Parent/Guardian (Children only) TEL: Carer TEL: Family Nursing & Home Care Nurse TEL:
9.	Precautions – Under what circumstances should buccal midazolam <u>not</u> be used? (e.g. other medication already administered in the last minutes)
All occasions when buccal midazolam is administered must be recorded (see back page)	
This plan has been agreed by the following:	
Prescribing Medical Practitioner (BLOCK CAPITALS)	Signature: Date:
Patient (BLOCK CAPITALS)	Signature: Date:
Parent/Guardian (for children only) (BLOCK CAPITALS)	Signature: Date:
Head Teacher (schools only) or Care Home/Agency Manager (BLOCK CAPITALS)	Signature: Date:
Family Nursing & Home Care Nurse (BLOCK CAPITALS)	Signature: Date:
A record must be kept of all persons trained to administer Buccal Midazolam.	

Authorised Person(s) trained to administer buccal midazolam to:

Name of Patient/Child: Date of Birth: URN:		DATES OF TRAINING		
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Name (BLOCK CAPITALS)	Signature Date	Buccal Midazolam	Basic Life Support	First Aid
Agreed by Patient/ Parent/Guardian (BLOCK CAPITALS)	Signature Date	Position		
Agreed by Head of School/Care Home Manager/Agency Manager/FNHC Nurse (BLOCK CAPITALS)	Signature Date	Position		
<p>Original document to be kept in patient/child's records with copies to other relevant parties involved in the patient/child's care.</p> <p>Date for review of plan:</p> <p>Copy holders to be notified of any changes by:</p>				
<p><i>This form should be updated every 12 months or when dosage is changed</i></p>				

Individual Health Care Plan for the Management of Prolonged Seizures

Record of use of Buccal Midazolam

Patient/Child's Name: **Date of Birth:** **URN:**

Date			
Time			
Administered by (Print name and Sign)			
Witnessed by (Print name and sign)			
Type of seizure			
Length and/or number of seizures			
Initial dosage of buccal midazolam given			
Outcome			
Observations			
Carer/Parent/Guardian informed (date & time)			
Prescribing practitioner informed (date & time)			
Head Teacher / Care Home / Agency Manager informed (date & time)			
Family Nursing & Home Care Nursing Sister informed (date & time)			
Other information			
Date buccal midazolam re-ordered			
Name of person re-ordering			

Competence in Clinical Skills

Existing FNHC 'Competence in Clinical Skills' document to be inserted in here