



Family Nursing & Home Care

**Policy and Standard
Operating Procedures
for administration of
Buccal Midazolam to Adults
who have prolonged
epilepsy seizures**

1 September 2021

Document Profile

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Title	Policy and Standard Operating Procedures for Administration of Buccal Midazolam to Adults who have prolonged epilepsy seizures
Author	Updated by Mo de Gruchy
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Version control / changes made

Date	Version	Summary of changes made	Author
April 2021	1.2	<p>Complete review</p> <p>Update of training requirements for administration and assessment of competence using ESNA Guidelines and Competency Checklist</p> <p>Update of guidance on delegation to non-registered FNHC and non-FNHC staff</p> <p>Reference list amended and updated</p> <p>Appendices amended and updated</p> <p>HSS document 'Individual Health Care Plan for the Treatment of Prolonged Seizures' removed as no longer in use</p>	Mo de Gruchy

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This Policy and Standard Operating Procedures were originally 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).

1. INTRODUCTION

1.1 Rationale

This clinical policy and Standard Operating Procedures (SOPs) have been developed to enable Family Nursing & Home Care (FNHC) Registered Nurses to administer Buccal Midazolam preparations for the emergency treatment of adults with prolonged epilepsy seizures. It also provides guidance for FNHC Registered Nurses to train non-registered FNHC staff and non-FNHC staff on the correct administration of the Buccal Midazolam preparations available as outlined.

In the UK and Ireland, there has been an emphasis on personalised epilepsy care in the community. Buccal midazolam is now recognised as the first line rescue treatment. It is a far more acceptable treatment to both administer and receive compared to rectal benzodiazepines or paraldehyde, which prior to the advent of buccal midazolam, were the recommended treatments. It is recognised that prompt administration of midazolam prevents or reduces the risk of seizures evolving into status epilepticus, resulting in improved outcomes for the patient (ESNA 2019).

FNHC 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.

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 may provide training to others, including non-FNHC staff, in the administration of Buccal Midazolam in the community

This clinical policy 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 Role and Responsibilities

Chief Executive Officer

The Chief Executive Officer has ultimate responsibility for ensuring that FNHC has robust governance measures in place to support the safety of patients related to the administration of buccal Midazolam.

Head of Quality Governance and Care

The Head of Quality Governance and Care is responsible for ensuring that FNHC has evidence based procedural documents available to ensure safe administration of buccal midazolam and that these are reviewed at appropriate intervals. They are also responsible for monitoring any incidents relating to this practice and the implementation of any action required to prevent reoccurrence of untoward incidents.

Operational Leads

Operational leads are responsible for ensuring that their teams have access to this policy/SOPs and for overseeing the monitoring of staff competence and attendance at any training. They also have a responsibility to ensure that any untoward incidents are investigated and action taken as necessary to mitigate risk.

All staff

All staff involved in administration of buccal midazolam have a responsibility to adhere to this policy/SOPs and to report any untoward events related to this practice.

2. POLICY

2.1 Buccal Midazolam Presentations

- Midazolam is a short-acting benzodiazepine that 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 2020). NICE (2020) 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 the Misuse of Drugs (Jersey) Law 1978 & Customs and Excise (Jersey) Law 1999 govern its use. It is exempt from storage and recording regulations.
- Buccal Midazolam is available under different trade names e.g. Buccolam® and Epistatus®. As Epistatus® is only for administration to children from age 10 to under 18, Buccolam® is the preparation of choice locally and will be the medication referred to throughout this Policy/SOPs.
- Buccolam® oromucosal solution (Shire Pharmaceuticals 2020a) is a clear colourless liquid. It is supplied in a prefilled, single-use oral syringe. Each syringe is colour coded and contains the prescribed dose for a particular age range:

2.2 Licensed Indication/Use

- Buccolam® is the first buccal Midazolam licensed product. It has a paediatric license to treat prolonged, acute convulsive seizures from the ages from 3 months up to and including 17 years. This is 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 policy and SOPs.
- Buccal Midazolam which has been prescribed by a hospital doctor/GP 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 policy and SOPs and in accordance with the FNHC Medicines Policies.

2.3 Authorisation to Administer Buccal Midazolam

- The administration of buccal midazolam for an emergency situation must be authorised by a Registered Prescriber on a Buccal Midazolam Care Plan/Treatment Protocol (Appendix 1) or in the patient’s nursing record.

2.4 Supply of Buccal Midazolam

- The patient will have their own buccal midazolam prescribed for them. This product must contain a Pharmacy dispensed label with the patient’s name and clear directions for use.

2.5 Storage of Buccal Midazolam

- Buccal Midazolam should be stored in accordance with the manufacturer’s information: Syringes of Buccolam® must be kept in the protective plastic tube until used. The product must not be refrigerated or frozen
- Buccal 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 Buccal Midazolam staff should advise those who are of the correct arrangements.

2.6 Training

- As a minimum, the administration of Buccal Midazolam should be undertaken by FNHC staff who have been deemed competent to do so and have received training in administration and assessment of competence, as recommended by ESNA (2019 and 2021) (Appendix 2 & 3).
- It is the responsibility of the individual’s line manager to determine their staff’s suitability to administer buccal midazolam according to FNHC policies and procedures (also see 2.8).

- FNHC staff may also be requested by others e.g. paid/informal carers to train them in the administration of Buccal Midazolam (see 2.9).

2.7 Multi-Agency Working

- Where FNHC staff are working in collaboration with other agencies e.g. Registered Providers, use of a Buccal Midazolam Care/Treatment Protocol (Appendix 1) should be encouraged. Completion of this care plan/protocol 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.

2.8 Administration of Buccal Midazolam by FNHC staff (except Home Care Service staff)

- The following FNHC staff are authorized to administer Buccal Midazolam:
 - Registered Nurses
 - FNHC non-registered staff in nursing teams. The non-registrant must hold a current NVQ/QCF/RQF Level 3 Medication Module certificate and have been deemed competent to administer Buccal Midazolam following successful completion of all necessary training and assessment of competence (appendix 2&3). A record of this should be kept as part of their knowledge and skills portfolio
- The Registered Nurse should also ensure the Buccal Midazolam Care/Treatment Protocol (Appendix 1) is completed and is discussed with and understood by the patient and anyone who may be required to administer Buccal Midazolam.

2.9 Administration of Buccal Midazolam by others (including Home Care Service staff)

- There may be times when it is appropriate for the Registered Nurse to train others in the administration of Buccal Midazolam, such as carers working for Registered Providers and/or informal (unpaid) carers.
- Administration of medications orally by carers employed by Registered Providers is considered an 'acceptable task', as per [JCC Personal Care and Clinical Tasks Guidance for Adult Social Care 2019](#).
- The Registered Nurse providing the training should confirm and document that the individual understands the information and instructions provided and has agreed to undertake this task.
- In this instance training on the administration of Buccal Midazolam should include:
 - information about the medication including safe storage arrangements
 - administration of Buccal Midazolam and care following administration (see SOPs in section 3)
 - the necessary documentation that needs to be completed

2.10 Disposal of Buccal Midazolam

- The healthcare professional should advise the patient to return expired Midazolam to a community pharmacy for safe disposal.

2.11 Reporting Adverse Drug Reactions (ADRs)

- In the event of an adverse reaction, immediate action should be taken to minimise the harm to the adult. Inform the prescribing medical practitioner and GP of the actions taken and record in the person's notes. In the event of an ADR, this 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')
<http://www.mhra.gov.uk/yellowcard>

3. STANDARD OPERATING PROCEDURES

3.1 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®

The principles of safe administration of medicines must be followed as per the latest version of the Family Nursing & Home Care Medicines Policy.

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

- 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 prefilled 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.

3.2 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 patient'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 is disposed of safely.
- Relatives/carers/significant others 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.
- Significant changes in the frequency of administration should be brought to the attention of the prescribing clinician.
- Re-order Buccal Midazolam to maintain adequate stock.

4. CONSULTATION PROCESS

Name	Title	Date
Judy Foglia	Director of Governance Regulation and Care	21.05.2021
Clare Stewart	Operational Clinical Lead for Out of Hospital Services	21.05.2021
Tia Hall	Operational Lead for Adult Services	21.05.2021
Teri O'Connor	Home Care Manager	21.05.2021
Elsbeth Snowie	Clinical Effectiveness Facilitator	10.05.2021
Justine Bell	Education and Practice Development Nurse	21.05.2021 17.08.2021

5 IMPLEMENTATION PLAN

Action	Responsible Person	Planned timeline
Email to all staff	Secretary/Administration Assistant (Quality and Governance Team)	Within 2 weeks following ratification
Policy to be placed on the organisation's Procedural Document Library	Secretary/Administration Assistant (Quality and Governance Team)	Within 2 weeks following ratification

6 MONITORING COMPLIANCE

Compliance with this policy and SOPs should be monitored by Team Leaders as part of their oversight of patient care. Incident and near miss reporting using Assure will inform learning and potential reviews associated with medicines management.

7. EQUALITY IMPACT STATEMENT

Family Nursing & Home Care is committed to ensuring that, as far as is reasonably practicable, the way services are provided to the public and the way staff are treated reflects their individual needs and does not discriminate against individuals or groups on any grounds.

This policy document forms part of a commitment to create a positive culture of respect for all individuals including staff, patients, their families and carers as well as community partners. The intention is to identify, remove or minimise discriminatory practice in the areas of race, disability, gender, sexual orientation, age and 'religion, belief, faith and spirituality' as well as to promote positive practice and value the diversity of all individuals and communities.

The Family Nursing & Home Care values underpin everything done in the name of the organisation. They are manifest in the behaviours employees display. The organisation is committed to promoting a culture founded on these values.

Always:

- ✓ Putting patients first
- ✓ Keeping people safe
- ✓ Have courage and commitment to do the right thing
- ✓ Be accountable, take responsibility and own your actions
- ✓ Listen actively
- ✓ Check for understanding when you communicate
- ✓ Be respectful and treat people with dignity
- ✓ Work as a team

This policy should be read and implemented with the Organisational Values in mind at all times. See Appendix 4 for the Equality Impact Assessment for this policy.

8 GLOSSARY

Buccal cavity - The area of the oral cavity between inner lining of the cheek and gums

Registered Prescriber - An individual currently registered to prescribe medication in the course of professional practice.

Registered Provider – An individual or organization registered with the Jersey Care Commission and thereby authorized to provide certain care activities

9 REFERENCES

Epilepsy Nurses Association (ESNA) (2019) *Best practice Policy for training professional carers in the administration of Buccal (Oromucosal) Midazolam for the treatment of prolonged and / or clusters of epileptic seizures in the community* Available at: <https://ilaebritish.org.uk/content/uploads/2019/06/ESNA-Midazolam-Policys.pdf> Last accessed 6th April 2021

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Government of Jersey (2021b) *Prescribed List: Products available as Pharmaceutical Benefit under the Health Insurance (Jersey) Law 1967 (including Dental Practitioners' Formulary)* Available at: <https://www.gov.je/SiteCollectionDocuments/Health%20and%20wellbeing/ID%20Prescribed%20List%20of%20Pharmaceutical%20Products.pdf> Last accessed 8th April 2021

Jersey Care Commission (2019) *Personal Care and Clinical Tasks Guidance for Adult Social Care*. Available at: <https://carecommission.je/wp-content/uploads/2019/03/JCC-Guidance-personal-care-and-clinical-tasks-adult-social-care-ratified-20190314.pdf> Last accessed 7th April 2021

NICE (2020) NICE Pathway, Treating Prolonged or Repeated Seizures and Convulsive Status Epilepticus, <http://pathways.nice.org.uk/pathways/epilepsy> Last accessed 6th April 2021

Shire Pharmaceuticals Ltd (2020a) *Buccolam Oromucosal Solution: Summary of Product Characteristics*. Available at: <https://www.medicines.org.uk/emc/product/2768/smpc> Last accessed 6th April 2021

Shire Pharmaceuticals Ltd (2020b) *Buccolam Oromucosal Solution: Patient Information Leaflet..* Available at: <https://www.medicines.org.uk/emc/files/pil.2768.pdf> Last accessed 6th April 2021

Southern Health NHS Foundation Trust (2021) *Policy for training in and administration of Midazolam Hydrochloride Oromucosal Solution (Buccolam®) 10mg/2ml for the Management of Tonic - Clonic Status Epilepticus in Adults with a Learning Disability* Available at [Policys for training in and administration of Midazolam Hydrochloride Oromucosal SolutionV6 \(2\).pdf](#) Last accessed 9th April 2021

10 APPENDIX

Appendix 1 Buccal Midazolam Care/Treatment Protocol

Buccal Midazolam Care/Treatment Protocol (adapted from SHNHSFT 2021)

The Treatment Plan must clearly specify the exact intervals when medication is to be administered in an epileptic seizure. The individual Treatment Plan is prescribed by an epilepsy specialist in collaboration with the community nurse, carer and patient.

(Please use language appropriate to the lay person when completing this form)

Patient's Name: Date of Birth: Address: Date operational from: Review Date: Completed by:
Seizure classification and description of seizures which may require buccal midazolam:
After how long of seizure activity should buccal midazolam be administered?
What is the first dose of midazolam that should be administered?
If there are difficulties in the administration of midazolam what actions should be taken?
What is the patient's usual reaction to buccal midazolam?
Can a second dose of buccal midazolam be given? After how long can a second dose of buccal midazolam be given? How much buccal midazolam is given as a second dose?
What is the maximum dose that can be given in 24 hours?
When should 999 be dialled for emergency help?
When should the patient's GP be consulted?

Who should witness the administration of buccal midazolam?
Who needs to be informed? (Carer/GP/Community Nurse etc. and contact details)
Under what circumstances should buccal midazolam NOT be given e.g. Rectal diazepam already recently administered?

ALL OCCASIONS WHEN BUCCAL MIDAZOLAM IS ADMINISTERED MUST BE RECORDED

This Plan has been agreed by the following:

Prescribing Doctor: Name (please print)
Signature Date

Community Nurse: Name (please print)
Signature Date

Carer/Guardian: Name (please print)
Signature Date

Day Services: Name (please print)
Signature Date

Respite Care: Name (please print)
Signature Date

Patient: Name (please print)
Signature Date

If the patient does not have the capacity to consent to the use of buccal midazolam a statement to that effect should be written here by the epilepsy specialist/prescriber.

Signature:

Date:

AUTHORISED PERSON(S) TRAINED TO ADMINISTER BUCCAL MIDAZOLAM

Patient's Name: _____

DOB: _____

NAME
.....Signature.....Date.....
(Block capitals)

NAMESignature Date
(Block capitals)

NAMESignature Date
(Block capitals)

NAMESignature Date
(Block capitals)

NAMESignature Date
(Block capitals)

THIS FORM SHOULD BE KEPT IN THE PATIENT'S MAIN FILE AND WITH THEIR MEDICATION CHART

Expiry date of this form

Appendix 2 ESNA (2019) Best practice training guidelines

ESNA (2019) Best practice guidelines for training professional carers in the administration of Buccal (Oromucosal) Midazolam for the treatment of prolonged and / or clusters of epileptic seizures in the community

It is recommended that the initial training should be four to six hours, and subsequent two yearly refresher training should last two to three hours.

Core components of an Epilepsy Awareness and Administration of Buccal Midazolam training course

Epilepsy Awareness

- ✓ What is epilepsy
- ✓ What causes epilepsy
- ✓ How do we make a diagnosis including differential diagnosis
- ✓ Types of seizures
- ✓ Treatment options
- ✓ First aid
- ✓ Status epilepticus
- ✓ Care planning and recording mechanisms
- ✓ Risk assessment
- ✓ SUDEP (Sudden Unexpected Death in Epilepsy)
- ✓ Interactive case discussions
- ✓ Sources of support and information

Administration of buccal midazolam

*All these components are essential

- ✓ What is midazolam, including different preparations / concentrations
- ✓ Indications for the use of midazolam
- ✓ Appropriate doses when given via the buccal route
- ✓ Benefits of using buccal midazolam
- ✓ Recognise signs of respiratory depression
- ✓ Possible difficulties in administration (e.g. excessive salivation, injury to mouth etc)
- ✓ Potential side effects
- ✓ Actions if buccal midazolam is ineffective
- ✓ Identifying and using individual's buccal midazolam care plan
- ✓ Secure storage and safe disposal
- ✓ Duty of care/ responsibility and accountability
- ✓ Practical demonstration using DVD or visual aids and use of water to demonstrate on a volunteer
- ✓ When to seek medical help
- ✓ Aware of potential for misuse
- ✓ Awareness of relevant local policies
- ✓ Interactive case discussions

Assessment of learning

There are recognised difficulties associated with the assessment of knowledge and skills of participants undertaking the training of buccal midazolam. Ongoing assessment using questioning during training is essential to ensure safety and professional carers' understanding. ESNA, in conjunction with Virtual College, has developed an external national online test in order to provide an independent assessment of training. It is recommended that this resource is used alongside the trainer's assessment of competence (see Appendix 3).

Appendix 3 Competency Checklist

[FNHC Buccal Midazolam Competency Checklist.pdf](#)



Family Nursing
& Home Care

COMPETENCY CHECKLIST

for the administration of Buccal (Oromucosal) Midazolam



Adapted with permission for use by FNHC from the original document available at www.esna-online.org

<https://esna-online.org/>

Appendix 4 Equality Impact Screening Tool

Stage 1 - Screening			
Title of Procedural Document: Policy and Standard Operating Procedures for Administration of Buccal Midazolam to Adults who have prolonged epilepsy seizures			
Date of Assessment	August 2021	Responsible Department	Clinical
Name of person completing assessment	Mo de Gruchy	Job Title	Quality Performance and Development Nurse
Does the policy/function affect one group less or more favourably than another on the basis of :			
	Yes/No	Comments	
• Age	No		
• Disability (Learning disability; physical disability; sensory impairment and/or mental health problems e.g. dementia)	No		
• Ethnic Origin (including hard to reach groups)	No		
• Gender reassignment	No		
• Pregnancy or Maternity	No		
• Race	No		
• Sex	No		
• Religion and Belief	No		
• Sexual Orientation	No		
If the answer to all of the above questions is NO, the EIA is complete. If YES, a full impact assessment is required: go on to stage 2, page 2			
Stage 2 – Full Impact Assessment			
What is the impact	Level of Impact	Mitigating Actions (what needs to be done to minimise / remove the impact)	Responsible Officer
Monitoring of Actions			
The monitoring of actions to mitigate any impact will be undertaken at the appropriate level			