



Family Nursing & Home Care

Policy and Standard Operating Procedures for Administration of Buccal Midazolam to Children 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 Children who have prolonged epilepsy seizures
Author	Updated by Faye Blest/Lyn Vidler (CCNT), with support from Mo de Gruchy (Governance team)
Category	Clinical
Description	To provide a policy and guidance for the safe use of Buccal Midazolam in children who have prolonged epilepsy seizures, to ensure patient safety.
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Version control / changes made

Date	Version	Summary of changes made	Authors
April - August 2021	1.2	<p>Complete review</p> <p>Removed previous statement re administration of Buccal Midazolam supplied in a bottle.</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>	Mo de Gruchy Lyn Vidler

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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 and trained healthcare professionals to administer buccal midazolam preparations for the emergency treatment of children and young people with prolonged epilepsy seizures. It also provides guidance for FNHC Registered nurses within the Child and Family Services 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 children/young people 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 provide training to others including non-FNHC staff for the administration of buccal midazolam (e.g. schools, care homes) 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. GUIDANCE

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 children and young people 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. It is recognized that prompt administration of midazolam prevents or reduces the risk of seizures evolving into status epilepticus, resulting in improved outcomes for patients (ESNA 2019).
- 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.
- 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 the prescribing medical practitioner on either the 'Royal College of Paediatrics and Child Health Epilepsy Passport' (Appendix 1) or in the child/young person's nursing record.

2.4 Supply of Buccal Midazolam

- The patient will have their own buccal midazolam. This product must contain a Pharmacy dispensed label with the child/young person's name and clear directions for use.
- It is the parent's responsibility to supply the buccal midazolam so it can be accessed by whoever may be caring for their child, both inside and outside of the home environment.
- FNHC staff caring for such children/young people must ensure that they are aware of how/where to access this medication should its use be required in an emergency.

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 midazolam (the exception being at Mont a L'Abbe school), 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, 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 Family Nursing and Home Care staff are working in collaboration with other agencies e.g. schools, use of the 'Royal College of Paediatrics and Child Health Epilepsy Passport' (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.

2.8 Administration of Buccal Midazolam Preparations by FNHC 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 'Royal College of Paediatrics and Child Health Epilepsy Passport' (appendix 1) is completed and is discussed with the young person/parent/guardian and anyone else who may be required to administer buccal midazolam.

2.9 Administration of Buccal Midazolam by others

- There may be times when it is appropriate for the Registered Nurse to train others in the administration of buccal midazolam, such as parents, foster parents, nursery and school staff.
- 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 young person/parent/guardian to return expired midazolam to a community pharmacy for safe disposal.

2.11 Reporting Adverse Drug Reactions (ADR)

In the event of an adverse reaction, immediate action should be taken to minimise the harm to the child/young person. Inform the prescribing medical practitioner and GP of the actions taken and record in the child/young 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 including the recording of the administration 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 child's head with something soft. If the child 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 child'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 child following administration of Buccal Midazolam

Purpose

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

Scope

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

Core Requirements

After the administration of buccal midazolam:

- Stay with the child after administration. Maintain close observation and monitor their condition and breathing. As the seizure subsides, check airway and breathing. If breathing, put into recovery position until he/she recovers consciousness. If not breathing perform CPR.
- Initial effects 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 child's condition within approximately five minutes then telephone for an ambulance immediately or follow the child's care plan.
- Once the child has recovered, write down the date, time and dose given of buccal midazolam on the medication form and document in the child's Emis record.
- Ensure that all used equipment is disposed of safely.
- Relatives/carers should be informed at the earliest opportunity that buccal midazolam has been administered.
- Significant changes in frequency of administration should be brought to the attention of the child's paediatrician.
- Parents to be advised to re-order buccal Midazolam from their child's paediatrician to maintain adequate supply.

4. CONSULTATION PROCESS

Name	Title	Date
Judy Foglia	Director of Governance Regulation and Care	17/08/2021
Michelle Cumming	Operational Lead for Child and Family Services	17/08/2021
Elsbeth Snowie	Clinical Effectiveness Facilitator	17/08/2021
Justine Bell	Education and Practice Development Nurse	17/08/2021
Gill John	Team Lead for CCNT	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 /SOPs policy 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

A statement to show that the document does not discriminate against disadvantaged or vulnerable people

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 3 for the Equality Impact Assessment for these guidelines.

8. GLOSSARY

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

Non-healthcare worker/individual- parent, nursery staff, teaching assistant

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

9 REFERENCES

Epilepsy Nurses Association (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* Available at: <https://ilaebritish.org.uk/content/uploads/2019/06/ESNA-Midazolam-Policys.pdf> Last accessed 6th April 2021

Epilepsy Nurses Association (ESNA) (2021) *Oromucosal Midazolam Competency Checklist*. Available at www.epistatus.co.uk/downloads/Competency_Checklist_for_Oromucosal_Midazolam_Administration.pdf. Last accessed 17th August 2021

Government of Jersey (2021a) *Jersey General Hospital Formulary* Available at; <https://soj/depts/HSS/Documents/ID%20Jersey%20General%20Hospital%20Formulary%20SM.pdf> Last accessed 7th April 2021

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

Royal College of Paediatrics and Child Health (RCPCH) (2016) *RCPCH Epilepsy Passport*. Available at: [RCPCH_Epilepsy_Passport_2016.pdf](https://www.rcpch.co.uk/sites/default/files/2016-12/RCPCH_Epilepsy_Passport_2016.pdf). Last accessed 11th June 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

Appendix 1 Front Sheet of Royal College of Paediatrics and Child Health
Epilepsy Passport (RCPCH 2016) [RCPCH Epilepsy Passport 2016.pdf](#)

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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 carer's 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.

Appendix 3 Competency Checklist

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



Family Nursing
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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 Children who have prolonged epilepsy seizures			
Date of Assessment	June 2021	Responsible Department	Child & Family
Name of person completing assessment	Lyn Vidler	Job Title	Children's Community Deputy Sister
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			