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**Buccal Midazolam for Prolonged**

**Epilepsy Seizures – Adult**

**Policy & Procedures**

**May 2025**

**Document Profile**

|  |  |
| --- | --- |
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**Version Control/Changes Made**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Version** | **Summary of changes** | **Author** |
| April 2021 | 1.2 | Complete review. Update of training requirements for administration and assessment of competence using ESNA Guidelines and Competency Checklist. Update of guidance on delegation to non-registered FNHC and non-FNHC staff. Reference list amended and updated. Appendices amended and updatedHSS document “Individual Health Care Plan forthe Treatment of Prolonged Seizures” removedas no longer in use. | Mo de Gruchy |
| May 2025 | 2.0 | Complete review. Updated Competency Checklist for the administration of Buccal (Oromucosal) Midazolam.2023 ESNA Guidelines – Trainers must now demonstrate specific competencies as outlined in the guidelines.Updated Appendices in accordance with updated guidelines.Glossary added. | Rachel Foster |
| June 2025 | 2.1 | Addition of Appendix 5 – Memo from Head of Education & Development | Rachel Foster |

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# INTRODUCTION

## Rationale

This clinical policy and procedures have been developed to enable Family Nursing & Home Care (FNHC) staff to administer buccal (oromucosal) midazolam preparations for the emergency treatment of adults with prolonged epileptic seizures. It also provides guidance for FNHC Registered Nurses to train non-registered FNHC staff and external personnel on the correct administration of buccal (oromucosal) midazolam, in line with current best practice.

In the UK and Ireland, there has been an increasing emphasis on personalised epilepsy care in the community. Buccal (oromucosal) midazolam is now recognised as the first-line rescue treatment for prolonged seizures. It is a more acceptable and practical alternative to rectal benzodiazepines or paraldehyde, which were previously recommended treatments. Prompt administration of midazolam has been shown to reduce the risk of seizures evolving into status epilepticus, leading to improved patient outcomes (ESNA, 2023).

FNHC is committed to ensuring that all patients receive a consistently high standard of care, regardless of who administers buccal (oromucosal) midazolam. Care must always be based on current best practice, with patient safety as the highest priority.

## Scope

This document applies to:

* FNHC staff who administer buccal (oromucosal) midazolam as indicated for the emergency treatment of prolonged epileptic seizures.
* FNHC staff who provide training to others, including non-FNHC personnel, on the correct administration of buccal (oromucosal) midazolam in the community.

This clinical policy and procedures outline the prescribing, supply, storage, and administration of buccal (oromucosal) midazolam. The administration of buccal (oromucosal) midazolam must be carried out in accordance with this document and the FNHC Medicines Policy.

For consistency, the term buccal (oromucosal) midazolam will be used throughout this document to refer to all available preparations. This medication is also known as midazolam oromucosal solution.

## 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 patient safety in relation to the administration of buccal (oromucosal) midazolam.

**Director of Governance and Care**

The Director of Governance and Care is responsible for ensuring that FNHC has evidence-based procedural documents in place to support the safe administration of buccal (oromucosal) midazolam. They must also ensure that these documents are reviewed at appropriate intervals. Additionally, they are responsible for:

* Monitoring incidents related to this practice.
* Implementing actions to prevent the recurrence of untoward incidents.

**Line Managers**

Line Managers are responsible for:

* Ensuring that their teams have access to this policy and procedures.
* Overseeing staff competency monitoring and ensuring attendance at any mandatory training provided by FNHC.
* Investigating untoward incidents and taking appropriate action to mitigate risks.

**All Staff**

All staff involved in the administration of buccal (oromucosal) midazolam have a responsibility to:

* Adhere to this policy and procedures.
* Report any untoward events related to this practice.

# POLICY

## Buccal (Oromucosal) Midazolam Presentations

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

Buccal (oromucosal) midazolam is indicated for the emergency treatment of status epilepticus and is the first-line treatment for adults with prolonged or repeated seizures in a community setting (NICE 2022).

Buccal (oromucosal) midazolam is available under different trade names such as:

* Buccolam® is the recommended preparation for adults in the UK and locally as it is licensed for use in adults and children.
* Epistatus® is only licensed for use in children aged 10 to under 18 years and is therefore not routinely used in adults.
* Buccolam® oromucosal solution (Shire Pharmaceuticals, 2022) is a clear, colourless liquid supplied in a prefilled, single-use oral syringe.

Each syringe is colour-coded and contains the prescribed dose for a specific age group.

## Licensed Indication / Use

Midazolam is classified as a Schedule 3 Controlled Drug (CD) under the Misuse of Drugs (Jersey) Law 1978 and the Customs and Excise (Jersey) Law 1999. However, it is exempt from storage and recording regulations.

Buccal (oromucosal) midazolam, when prescribed by a hospital doctor or GP for the emergency treatment of prolonged epileptic seizures, may be administered by FNHC staff.

Administration in these circumstances will be supported by FNHC, provided it is carried out in accordance with this policy and procedure document, and the FNHC Medicines Policies.

## Authorisation to Administer Buccal (Oromucosal) Midazolam

The administration of buccal (oromucosal) midazolam in an emergency situation must be authorised by a Registered Prescriber.

This authorisation must be documented in a Buccal Midazolam Care Plan/Treatment Protocol ([Appendix 3](#_Appendix_3_Buccal)) or recorded in the patient’s nursing record.

## Supply of Buccal (Oromucosal) Midazolam

Each patient must have their own prescribed buccal (oromucosal) midazolam.

The medication must be dispensed by a pharmacy and include a label with the patient’s name and clear directions for use.

## Storage of Buccal (Oromucosal) Midazolam

Buccal (oromucosal) midazolam must be stored in accordance with the manufacturer’s guidelines:

* Syringes of Buccolam® must be kept in their protective plastic tubes until use.
* The product must not be refrigerated or frozen.

Buccal (oromucosal) midazolam has the potential for misuse, therefore:

* Storage arrangements must ensure that the medication is securely stored yet accessible to authorised personnel.
* While FNHC is not usually responsible for the storage of buccal (oromucosal) midazolam, staff should advise individuals responsible for storage on correct procedures.

## Training

The administration of buccal (oromucosal) midazolam must only be undertaken by FNHC staff who have been deemed competent and have received comprehensive training in its administration. Training can be accessed by booking online via the Education and Development department’s [Eventbrite page](https://www.eventbrite.co.uk/o/family-nursing-home-care-9717951793).

This training must include:

* Understanding epilepsy and seizure types.
* The pharmacology of buccal (oromucosal) midazolam, including its effects, side effects, contraindications, and legal classification.
* Step-by-step administration techniques and best practice guidance.
* Recognising and managing adverse reactions.
* Legal, ethical, and governance considerations, including record-keeping and reporting requirements.
* Assessment of competence, with practical demonstrations and competency sign-off by a suitably qualified trainer.

Training must follow a structured format, as recommended by ESNA (2023), ensuring standardised content and competency assessment across all staff.

It is the responsibility of the individual’s line manager to assess their staff’s suitability to administer buccal (oromucosal) midazolam, ensuring compliance with FNHC policies and procedures.

The FNHC Education and Development department may also be requested by others, such as paid or informal carers, to provide training in the administration of buccal (oromucosal) midazolam. Training provisions must ensure that:

* It aligns with the ESNA (2023) competency framework.
* The trainee demonstrates a clear understanding and practical competence.
* The trainee is deemed able to administer midazolam safely.
* The effectiveness of training is monitored and reviewed periodically.

## Multi-Agency Working

When FNHC staff are working in collaboration with other agencies (e.g. Registered Providers), the use of a Buccal Midazolam Care Plan/Treatment Protocol should be actively encouraged.

This care plan/protocol should be completed collaboratively with:

* The prescribing medical practitioner.
* The patient.
* Other relevant parties involved in the patient’s care (e.g. family members, carers, or external healthcare professionals).

A multi-agency approach ensures that the administration of buccal (oromucosal) midazolam is safe, consistent, and aligned with best practice guidance, promoting continuity of care across different settings.

## Administration of Buccal (Oromucosal) Midazolam by FNHC Staff

*(excluding Home Care Service staff)*

The following FNHC staff are authorised to administer buccal (oromucosal) midazolam:

* Registered Nurses.
* FNHC non-registered staff working within nursing teams, provided they:
	+ Hold a current NVQ/QCF/RQF Level 3 Medication Module certificate.
	+ Have been deemed competent following successful completion of all necessary training and assessment of competence.
	+ Maintain a record of their training and competency assessment as part of their knowledge and skills portfolio.

The Registered Nurse must ensure that the Buccal Midazolam Care Plan/Treatment Protocol is:

* Completed in full.
* Discussed with and understood by the patient and any individuals who may be required to administer buccal (oromucosal) midazolam.

## Administration of Buccal (Oromucosal) Midazolam by Others

*(including Home Care Service staff)*

There may be occasions when it is appropriate for a Registered Nurse to train others in the administration of buccal (oromucosal) midazolam, such as:

* Carers employed by Registered Providers.
* Informal (unpaid) carers (e.g. family members).

The oral administration of medications by carers employed by Registered Providers is considered an ‘acceptable task’, as outlined in the JCC [Personal Care and Clinical Tasks in Adult Social Care - Guidance for Providers of Social Care in Home Care and Care Homes](https://carecommission.je/wp-content/uploads/2023/11/Guidance-Personal-Care-and-Clinical-Tasks-October-2023.pdf) (2023).

The Registered Nurse providing the training must:

* Confirm and document that the individual receiving training understands the information and instructions provided.
* Ensure the individual has agreed to undertake the administration of buccal (oromucosal) midazolam.

Training on the administration of buccal (oromucosal) midazolam should include:

* Information about the medication, including its effects, contraindications, and safe storage arrangements.
* Step-by-step guidance on administration, including care following administration.
* Correct documentation and record-keeping requirements.

## Disposal of Buccal (Oromucosal) Midazolam

The healthcare professional should advise the patient to return any expired or unused buccal (oromucosal) midazolam to a community pharmacy for safe disposal in accordance with medicines disposal regulations.

## Reporting Adverse Drug Reactions (ADRs)

If an adverse drug reaction (ADR) occurs, immediate action must be taken to minimise harm to the patient.

The prescribing medical practitioner and GP must be informed of the reaction and the actions taken. This must also be recorded in the patient’s notes.

All ADRs must be reported in line with FNHC’s Incident Reporting Policy.

Any suspected ADR should also be reported to the Medicines & Healthcare Products Regulatory Agency (MHRA) via the Yellow Card Scheme. Reports can be submitted online at:

[MHRA Yellow Card Scheme](https://yellowcard.mhra.gov.uk/)

#  PROCEDURE

## Administration of Buccal (Oromucosal) Midazolam from a Pre-Filled Oral Syringe

**Pre-Administration Checks**

Before use, always check the expiry date stated on the carton, tube, syringe labels and the individual has been prescribed the medication, which is clearly labelled with their details.

Do not use Buccolam® if:

* Any of the protective plastic tubes containing the syringes have been opened or damaged.
* The solution is not clear (e.g. cloudy or white crystal-like particles are present.
* The medication is expired.
* The individual has been administered the medication within the previous 24 hours (unless this is a prescribed second dose)

**Administration Procedure**

Take one plastic tube, break the tamper-proof seal, and remove the pre-filled syringe containing Buccolam®.

Remove and discard the red syringe cap before use to avoid choking.

Do not attach a needle to the syringe.

Each syringe is pre-filled with the prescribed dose for a single treatment.

Position the patient appropriately:

If the patient is lying down, cushion their head with something soft.

If the patient is seated, support their head against your body to keep their airway clear and free your hands for administration.

Administer the medication:

* Gently pull back the patient’s cheek, just enough to place the end of the syringe into the buccal cavity (the space between the gum and the cheek).
* Angle the syringe so that the tip is well inside the buccal cavity.
* Slowly press the syringe plunger to release the full amount of Buccolam® into the side of the mouth.
* Do not squirt the liquid forcefully or release it too quickly, as this may result in spillage.
* If necessary, split the dose, administering half on one side of the mouth and the other half on the opposite side to aid absorption.

**Care of the Patient Following Administration of Buccal (Oromucosal) Midazolam**

**Immediate Post-Administration Care**

Monitor the individual until they have recovered. They will need ongoing monitoring for up to 24 hours after administration.

Closely observe and monitor their condition, particularly their breathing and level of consciousness.

As the seizure subsides, check the airway and breathing:

If breathing, place the patient in the recovery position until they regain full consciousness.

If not breathing, commence CPR immediately and call for emergency medical assistance.

**Effectiveness of Buccal (Oromucosal) Midazolam**

The initial effect of midazolam should be apparent within approximately five minutes.

Monitor seizure activity closely.

If symptoms subside, continue monitoring and aftercare as per the patient’s care plan.

If there is no improvement within five minutes, call 999 for an ambulance immediately or follow the patient’s individualised care plan.

**Post-Recovery Actions**

Document the administration of buccal (oromucosal) midazolam in the patient’s records, including:

* Date and time of administration.
* Route of administration.
* Signature of the person administering the medication.

Keep used syringes to show paramedics what has been given.

Dispose of all used equipment safely in accordance with FNHC’s clinical waste disposal policies.

**Communication and Follow-Up**

Inform the patient’s relatives, carers, or significant others as soon as possible that buccal (oromucosal) midazolam has been administered. Ensure this is recorded in writing in the relevant documentation.

Report any significant changes in the frequency of administration to the prescribing clinician for further review.

Replenish stock of buccal (oromucosal) midazolam to ensure the patient has an adequate supply for future emergencies.

# MONITORING COMPLIANCE

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

# CONSULTATION PROCESS

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Date** |
| Claire White | Director of Governance & Care | 24 March 2025 |
| Elspeth Snowie | Head of Quality & Safety |
| Tia Hall | Operational Lead and Registered Manager for Adult Services |
| Teri O’Connor | Registered Manager – Home Care Service |
| Justine Le Bon Bell | Head of Education & Development |

# 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 always read and implemented with the Organisational Values in mind. See the Equality Impact Assessment for this policy.

## EQUALITY IMPACT SCREENING TOOL

|  |
| --- |
| **Stage 1 - Screening**  |
| Title of Procedural Document: **Buccal Midazolam for prolonged epilepsy seizures – Adult - Policy & Procedures** |
| Date of Assessment | **30/03/2025** | Responsible Department | **Clinical** |
| Completed by | **Rachel Foster** | Job Title | **Quality & Performance 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 Equality Impact Assessment is complete. If YES, a full impact assessment is required: go on to stage 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 |

# IMPLEMENTATION PLAN

|  |  |  |
| --- | --- | --- |
| **Action** | **Responsible Person** | **Planned timeline** |
| Policy to be uploaded to the Procedural Document Library | Education and Development Administrator | Within 2 weeks following ratification |
| Email to all staff  | Education and Development Administrator | Within 2 weeks following ratification |
| Upload policy (+/- assessment tool) to Virtual College and allocate to relevant staff | Education and Development Department | Within 2 weeks following ratification |
| Relevant staff to sign (via Virtual College) that they have read and understood policy. | All staff notified via Virtual College. | Within 2 months of notification |

# GLOSSARY OF TERMS

**Adverse Drug Reaction (ADR)**

An unwanted or harmful response to a medication. ADRs must be reported according to FNHC’s Incident Reporting Policy and the MHRA Yellow Card Scheme.

**Buccal (Oromucosal) Midazolam**

A short-acting benzodiazepine administered into the buccal cavity (the space between the gum and cheek) for the emergency treatment of prolonged or repeated seizures (status epilepticus).

**Buccal Cavity**

The area inside the mouth, between the gum and the inner cheek, where buccal (oromucosal) midazolam is administered.

**Buccal Midazolam Care Plan/Treatment Protocol**

A written document detailing the patient’s prescribed dosage, administration method, and emergency response plan.

**Controlled Drug (CD)**

A medication subject to legal restrictions due to the risk of misuse. Midazolam is a Schedule 3 Controlled Drug under the Misuse of Drugs (Jersey) Law 1978 but is exempt from storage and recording regulations.

**Epilepsy**

A neurological condition causing recurrent seizures due to abnormal brain activity.

**ESNA (Epilepsy Specialist Nurses Association)**

A professional body providing best practice guidelines for the training and administration of buccal (oromucosal) midazolam (latest guidance: ESNA 2023).

**Multi-Agency Working**

Collaboration between FNHC staff, healthcare professionals, and carers to ensure safe administration of buccal (oromucosal) midazolam.

**National Institute for Health and Care Excellence (NICE)**

A UK body providing evidence-based guidance on healthcare, including the emergency treatment of status epilepticus with buccal (oromucosal) midazolam (NICE 2022).

**Off-Label (Off-Licence) Use**

The use of a medication outside its licensed indications. For example, Buccolam® is licensed for use in children but is widely used off-label in adults for emergency seizure treatment.

**Prescribing Medical Practitioner**

A doctor or other authorised clinician who prescribes medications, including buccal (oromucosal) midazolam.

**Pre-Filled Oral Syringe**

A single-use syringe containing a pre-measured dose of Buccolam®, designed for direct buccal administration.

**Prolonged Seizure**

A seizure lasting more than five minutes. (NICE 2022)

**Repeated Seizure**

Three or more seizures within an hour. (NICE 2022)

**Seizure**

A sudden burst of abnormal electrical activity in the brain that can affect movement, awareness, or behaviour.

**Status Epilepticus**

A prolonged seizure lasting more than five minutes or repeated seizures without recovery, requiring emergency treatment with buccal (oromucosal) midazolam.

**Training and Competency Assessment**

A structured process ensuring that FNHC staff and trained carers are competent in the safe administration of buccal (oromucosal) midazolam, following ESNA 2023 standards.

**Yellow Card Scheme**

The MHRA’s official system for reporting adverse drug reactions (ADRs) to improve medicine safety monitoring.

# REFERENCES

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# APPENDICES

## Appendix 1 Best Practice Training Guidelines – Summary of changes in 2023 update

|  |  |  |
| --- | --- | --- |
|  | 2019 ESNA Best Practice Guidelines | 2023 ESNA Interim Best Practice Guidelines |
| Trainer Competencies | Did not categorise different groups of trainers; general competency was required. | Introduces three competency levels: Group 1 (training individuals and carers), Group 2 (training carers outside clinical settings), and Group 3 (Train the Trainer courses). Each group has specific qualifications and CPD requirements. |
| Delivery of Training Courses | No specified minimum duration for training or refresher courses; training topics were outlined but not structured. | Initial training must be at least six hours face-to-face; refresher training must be at least three hours every two years. Training content expanded to include detailed epilepsy overviews, seizure management, practical demonstrations, and risk assessments. |
| Assessment of Learning | Emphasised the need for assessing knowledge but did not specify assessment methods; recommended an online test, which had low uptake. | Replaces the online test with continuous assessment using written evaluations and questioning; introduces a Carers Competency Checklist for competency appraisals. |
| Responsibilities | Stated that professional carers should receive training updates every two years. | Reinforces biennial refresher training; increasing patient, family, and carer involvement in care plans; training must be sourced from trainers who meet all competency standards. |

## Appendix 2 Interim 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

Pages 5 – 8. Please [click here](https://esna-online.org/wp-content/uploads/2024/01/Midazolam-interim-guidelines-MI_12454014_21.12.23_V_3.pdf) to view the full document

## Appendix 3 Buccal Midazolam Care / Treatment Procol

The Treatment Plan must clearly state the specific time intervals at which medication should be given during a seizure. It should be written by an epilepsy specialist in collaboration with the community nurse, the carer, and the patient. Please ensure the language used on this form is clear and easy to understand for those without medical training. (adapted from ESNA 2023)

|  |  |
| --- | --- |
| **Name** | **Date of Birth** |
| **Address** |
| **Known Allergies** |
|  |
| **Description of seizures which may require buccal midazolam:** |
| 1. Usual duration of seizure:
 |
| 1. Usual duration of seizure:
 |
| 1. Usual duration of seizure:
 |
| 1. Usual duration of seizure:
 |
|  |
| Other useful information: |
|  |
| **Midazolam Treatment Plan** |
| 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. Initial dosage: How much buccal midazolam is given initially?Prescribing weight (if relevant): |
| 3. What is the usual reaction(s) to buccal midazolam? |
| 4. If there are difficulties in the administration of buccal midazolam, e.g. Excessive salivation, what action should be taken? |
| 5. Can a second dose of buccal midazolam be given? **Yes / No**This would be in exceptional circumstances following a multi-disciplnary discussion, the outcome of which should be recorded in medical records. It is recommended that an ambulance is called if a second dose is administered. |
| 1. When should 999 be dialed for emergency help? (*Please tick appropriate box*)

[ ]  If the full prescribed dose of midazolam fails to control the seizure after........... Minutes.[ ]  Other (please give details, e.g. If concerned about breathing, serious/head injury, unable to administer midazolam etc |
| 7. Precautions – maximum dose of midazolam to be administered in a 24-hour period |
| 8. When should the GP be consulted? |
| 9. Who should witness the administration of buccal Midazolam? |
| 10. Who needs to be informed? (*Carer/GP/Community Nurse etc. and contact details*) |
| 11. 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** |
| Prescriber / epilepsy specialist | Signature:Date: |
| Community Nurse | Signature:Date: |
| Patient / patient’s representative (note below): | Signature:Date: |
| Patient | 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** |
| Name | Signature | Date |
| Name | Signature | Date |
| Name | Signature | Date |
| Name | Signature | Date |
| Name | Signature | Date |
| **THIS FORM SHOULD BE KEPT IN THE PATIENT’S MAIN FILE AND WITH THEIR** **MEDICATION CHART** |
| This form is valid until date: |

## Appendix 4 Competency Checklist for the administration of Buccal (oromucosal) Midazolam



**Double Click the image to open the Competency Checklist**

## Appendix 5 – Memo from the Head of Education & Development