






# BUCCAL MIDAZOLAM

<b>VERSION No</b>	2	
<b>REVIEWED BY</b>	Clinical Lead (RQ)	
<b>NUMBER OF PAGES</b>	5	

## Introduction









*Epilepsy is a common condition with an incidence of 80 per 100,000 people. At least 20% of people with a learning disability across their lifespan have epilepsy.*

-  *Chronic epilepsy is more likely to occur in people with a learning disability.*
-  *Tonic - clonic status epilepticus is defined as prolonged or recurrent tonic – clonic seizures persisting for 30 minutes or more. Early treatment of tonic – clonic seizures in the premonitory stage of status epilepticus reduces morbidity and mortality.*
-  *Until recently, the most commonly used medication was rectal diazepam. Buccal midazolam provides an alternative treatment to rectal diazepam for tonic - clonic status epilepticus. Buccal midazolam is initiated on a named person basis by an epilepsy specialist who will determine the suitability of the individual for buccal midazolam and the dose required.*
-  *The administration of buccal midazolam is considered to be a less invasive procedure than the administration of rectal diazepam and the issues of privacy and dignity are less compromised*













## Legal Status

*Midazolam is not licensed for buccal use and this has to be explained to the family or relevant person and the individual, by the epilepsy specialist. (Midazolam Buccal Liquid is an 'Unlicensed Medicine' within the meaning of current legislation governed by the UK Medicines Acts and EU Pharmaceutical Directives.) It is recognised that the administration of buccal midazolam for the control of prolonged, continuous or cluster of seizures is an effective treatment which can be lifesaving. This has resulted in its inclusion in the National Institute for Health and Clinical Excellence (NICE) clinical practice guideline on the diagnosis and management of epilepsy in children and adults last updated in February 2016. NICE Guidelines (CG137). Midazolam is a controlled drug and is stored, dispensed and administered in line with this organisations Policy and Procedures medication policy which includes controlled drugs.*





## Procedure

-  Buccal midazolam is initiated on a named person basis by an epilepsy specialist who will determine the suitability of the individual for buccal midazolam and the dose required
-  the epilepsy specialist will explain to the family or their representative and the individual that midazolam is not licensed for buccal use and is a controlled drug
-  the individual will have a personalised management protocol agreed by the epilepsy specialist, community nurse, family or representative and the individual wherever possible
-  clear instructions will be in place for buccal midazolam administration in the individuals medication treatment plan
-  the training of staff to administer buccal midazolam will be tailored to each individual
-  there must always be a current and valid prescription
-  the efficacy and use of midazolam will be monitored, by nursing staff, who will ensure the epilepsy specialist is updated
-  normal procedures to ensure the safe administration of medicine must be followed















## Initial Treatment


-  as buccal midazolam can cause severe drowsiness, the solution should not normally be administered until after the seizure has lasted 5 minutes
-  however, in exception to the recommended 5 minute delay, individuals known to suffer tonic-clonic seizures that usually last more than 5 minutes with loss of consciousness should be advised to administer midazolam immediately or even at the first indicative signs of seizure onset and for those individuals, until experience indicates otherwise, it may be advisable to call an ambulance without delay.
-  the usual dose for a person aged 10 years and over is 10mg (ten milligrams) of Epistatus®, however, the dose should be checked if other products are prescribed
-  using the oral syringe provided, half of the prescribed dose is administered to each side of the buccal cavity (between the lower gums and cheeks)
-  if this is not possible, then the whole dose is administered to the buccal cavity on one side of the mouth
-  the dose must not be administered below the tongue since the teeth may clamp shut and break the syringe in the mouth
-  in cases of excessive salivation Epistatus® can be administered intra-nasally
-  in normal circumstances an ambulance should be called at the same time as the first dose of midazolam is administered, however, if it is known that the service user usually responds positively to the first dose then the call for an ambulance should wait until the second dose is needed
-  ideally the individual should remain supine for at least an hour after administration
-  the patient will be drowsy for several hours after administration and may be protected from recurring seizures for up to four hours
-  The Individual will be drowsy for several hours after administration and may be protected from recurring seizures for up to four hours.
-  Depending on the individuals level of consciousness they may require to be placed into the recovery position to protect the person's airway.

## Repeat doses











-  initial effects become apparent after approximately 5 minutes, if no beneficial effect (that is reduction in seizure activity) is apparent 10 minutes after administering Midazolam, then another dose of 10mg (ten milligrams) is administered
-  If no beneficial effect is apparent 5 minutes after the second dose, then wait for the ambulance
-  no more than two doses of 10mg (ten milligrams) of midazolam should be administered in any 24 hour period
-  if both doses have been used and seizures continue an ambulance is called

## Administration of Intera Buccal Midazolam (Epistat)







-  wash your hands and put on disposable gloves
-  reassure the individual and explain to the person what is happening
-  open the bottle by pressing down on the lid
-  insert the syringe and withdraw the prescribed amount
-  sit the individual on a chair with their head supported
-  hold the chin to keep the head steady
-  gently open the mouth by holding their chin and gently applying downward pressure on their lower lip
-  insert the syringe horizontally into the back of their mouth, between the gum and their teeth
-  to locate the buccal cavity, gently tilt the syringe upwards and very slowly administer half the liquid
-  repeat the process in the opposite cavity
-  ensure the individual is safe and comfortable
-  Return the medication to the Controlled Drug cupboard.
-  wash hands and equipment and dispose of waste appropriately
-  sign the appropriate records for controlled drugs and the administration of Buccal Midazolam

 continue to monitor the individual

### Side Effects/Contraindication/Precautions and Treatment of Overdoses

-  always refer to and familiarise yourself with the Patient Information leaflet that is provided with each Epistatus pack dispensed
-  Drowsiness, prolonged sedation and ataxia are the most commonly reported side effect.
-  Nausea, vomiting, constipation, dry mouth and hiccup have also been reported
-  Respiratory depression may occur after 3 doses administered closely together, therefore, a third dose should only be administered in hospital
-  Buccal midazolam should be used with caution in service users with chronic respiratory insufficiency.
-  Severe irritation to mucous membranes may occur after nasal administration
-  Paradoxical reactions (e.g. agitation, involuntary movements, hyperactivity, hostility, aggression and excitement) have been reported, although these are rare
-  Contraindications include hypersensitivity and acute narrow angle glaucoma
-  The safety of midazolam in pregnancy and breastfeeding has not been established
-  Signs of respiratory depression and overdose may be indicated by excessive somnolence, confusion, hypotension, decreased respiratory rate and paradoxical excitation, an ambulance should be called immediately.



### Storage of Midazolam

-  Buccolam is available in cartons containing four pre-filled, orange-coloured syringes, the pack should be stored upright at 15-25oC and never be refrigerated or frozen
-  up to date information regarding the storage of buccal midazolam should always be obtained from the PIL provided with each pack
-  Buccal midazolam oral syringes must be kept in the protective plastic tube which must have an intact tamper evident seal
-  Buccal midazolam must be kept in a locked controlled drugs cupboard and recorded in the controlled drugs register
-  where buccal midazolam is used for leave purposes, it must be entered in and out of the controlled drugs register to maintain an audit trail
-  any buccal midazolam that needs to be destroyed must be done in accordance with guidelines for the destruction of controlled drugs

### Training

Epilepsy awareness training and buccal midazolam training is provided by an epilepsy specialist nurse. The core components for this training will meet Joint Epilepsy (JEC) guidelines. Only people who have been trained by a specialist will be asked to administer buccal midazolam. Records of competency in the administration of buccal Midazolam must be kept for every trained member of staff and reviewed regularly

### Related Guidance

-  *NICE clinical practice guideline on the diagnosis and management of epilepsy in children and adults last updated in February 2016. NICE Guidelines (CG137)*  
<https://www.nice.org.uk/Guidance/CG137>
-  *NHS* <http://www.southernhealth.nhs.uk/resources/assets/inline/full/0/84826.pdf>

*The Medication Plan must clearly specify the exact intervals when medication is to be administered in an epileptic seizure. The individual Medication Plan is prescribed by an epilepsy specialist (learning disability consultant or higher trainee), in collaboration with the community nurse, carer and individual.*

<b>Buccal Midazolam Medication Plan</b>	
<b>Name of Resident</b>	
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 individual'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 clients GP be consulted?	
Who should witness the administration of buccal midazolam?	
Who needs to be informed? (Parent / Carer / GP / Community Nurse etc. and contact details)	
Under what circumstances must Buccal Midazolam <b>NOT</b> 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:*

<b>Prescribing Doctor</b>		<b>Signature</b>	
		<b>Date</b>	
<b>Community Nurse</b>		<b>Signature</b>	
		<b>Date</b>	
<b>LPA / Representative / Advocate</b>		<b>Signature</b>	
		<b>Date</b>	
<b>RGN</b>		<b>Signature</b>	
		<b>Date</b>	
<b>Resident's Name</b>		<b>Signature</b>	
		<b>Date</b>	

*If the client 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.*

<b>Epilepsy Specialist's Name</b>		<b>Signature</b>	
		<b>Date</b>	

**APPENDIX 2:**

**Report form: Suspected reaction to Midazolam given as emergency treatment for Epileptic Seizures**

<b>Name</b>		<b>D.O.B.</b>	
<b>Time</b>			
<b>Dose</b>			
<b>Route</b>			

*Midazolam as a Buccal / Intranasal preparation is unlicensed. Please report all suspected reactions to the Consultant. Please give a clear account of the event.*

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<b>Signature</b>		<b>Date</b>	
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*Copy to be put in care plan and sent to relevant health professional*

**APPENDIX 3:**

**Record of staff members authorised to administer Buccal Midazolom**

<b>Name of Resident</b>				<b>D.O.B.</b>	
<b>Name</b>		<b>Signature</b>		<b>Date</b>	
<b>Name</b>		<b>Signature</b>		<b>Date</b>	
<b>Name</b>		<b>Signature</b>		<b>Date</b>	
<b>Name</b>		<b>Signature</b>		<b>Date</b>	
<b>Name</b>		<b>Signature</b>		<b>Date</b>	

*This form must be kept in the individuals care/support plan with their medication administration record / plan*

<b>Review Date of staff training</b>		<b>Reviewed by</b>	
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