



## Buccal Midazolam for emergency treatment of prolonged seizures Update June 2018

Buccal Midazolam is the drug of choice for emergency treatment of prolonged acute convulsive (breakthrough) seizures in children and adults.

- There are now two licensed products, (Buccolam 10mg/2ml and Epistatus 10mg/1ml). Both are only licensed in children (Buccolam 3 months to 18 years, Epistatus 10 years to 18 years).
- There are no currently licensed products for children under 3 months or for adults.
- Single dose buccal syringes are preferred for most patients apart from some young children under 3 months who require a smaller dose
- Use of pre-filled oral syringes facilitates rapid administration and reduces the risk of dose errors.
- **All prescribing should be by brand.**
- Each buccal syringe contains one dose of midazolam to be used to treat one breakthrough seizure
- Patients, newly prescribed buccal midazolam by secondary care. will receive a Joint Epilepsy Council protocol or epilepsy care plan, which details their dose and instructions for administration, This must be updated annually.
- Patients should remain under shared care with secondary care.
- Once established, on either Buccolam or Epistatus, patients should not be switched to an alternative brand
- If a patient does not require treatment with Midazolam in a 12 month period the need for ongoing prescription should be re-assessed and withdrawal considered.

This edition is also available on PathfinderRF  
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## Paediatrics

- **Buccolam 5mg/ml in a ready to use pre-filled buccal syringe is the preferred brand of buccal midazolam for children at NGH and KGH**
- All paediatric patients should now have been switched to Buccolam at their annual review
- Buccolam buccal syringes are age banded (according to dose) and colour coded
- Buccolam buccal syringes are available in boxes of 4. The pharmacy supplying Buccolam should label each syringe individually so that parents can store individual syringes in different locations if necessary.
- Paediatric patients being newly prescribed buccal midazolam by secondary care. will receive a Joint Epilepsy Council protocol, which details their dose and instructions for administration, from the Childrens' Epilepsy Specialist Nurse. This will be updated annually.
- Midazolam should be individually prescribed and a care plan must be completed.
- Unqualified carers must attend appropriate training prior to administration of midazolam. Guidance leaflets are available for school and nursery staff where required.
- For some patients younger than 3 months there is no suitable single dose preparation. For these patients midazolam 50mg/5mls oral solution (unlicensed special) in multidose bottles may be prescribed.

## Adults

- Adult patients especially if transitioning from children's services to adult services may be prescribed Buccolam 10mg/2mls (10mg dose).
- Some adult patients especially those requiring more than 10mg per dose are prescribed the Epistatus brand.
- Epistatus buccal syringes contain midazolam hydrochloride 10mg/1ml in ready to use pre-filled buccal syringes.
- Epistatus is available as a single unit
- For most patients, use of a licensed preparation is preferred, however, a small minority of patients may still require unlicensed midazolam 50mg/ml oral solution in multidose bottles.

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Addressograph

Appendix

Northampton General Hospital   
NHS Trust

## Guidance for the use of Emergency Rescue Medication for people with Epilepsy

Administration of Buccolam®/Epistatus® - (Midazolam Oromucosal Solution)  
pre-filled oral syringe

### 1.0 Why do we administer Buccal Midazolam?

- 1.1 The majority of people who have epilepsy usually recover within a short period of time after a seizure. However there are occasions when this does not happen and the person goes into a prolonged seizure and occasionally “Status Epilepticus”. The definition for a prolonged seizure will vary from person to person.
- 1.2 A person who has experienced a prolonged seizure or Status Epilepticus may be prescribed a medicine called midazolam which is given via the buccal route (hence the medicine is often referred to as ‘buccal midazolam’) for prolonged seizure. This medicine is always prescribed by the patient’s doctor/specialist epilepsy nurse.
- 1.3 There are different preparations of buccal midazolam and it is essential that training is accessed for the preparation prescribed.

### 2. Buccolam®/Epistatus

- 2.1 Buccolam® is a product that contains midazolam, and is used for the majority of children aged more than 3 months. For younger children, Epistatus multidose bottle will be used.  
  
Epistatus is a product that contains Midazolam and is used for the majority of adults.
- 2.2 Each dose Buccolam/Epistatus comes in a sealed tamper proof plastic tube containing one pre-filled ready to use oral syringe, (Buccolam is colour coded according to strength). Each oral syringe contains **one** dose of Buccolam/Epistatus which is a clear colourless liquid. There is a plastic cap on the end of the oral syringe. This must be removed before administering the medication.
- 2.3 The patient information that comes with Buccolam outlines colour coding for general age ranges. However there may be some circumstances where a pupil may be prescribed a dose outside this age range.

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- 2.4 Buccolam/Epistatus is a medication from the group of drugs called benzodiazepines that affect the central nervous system. It has muscle relaxant and anti-convulsant properties.
- 2.5 All medication has the potential to cause side effects. The side effects of Buccolam®/Epistatus may include drowsiness, shallow breathing (respiratory depression) confusion, nausea and vomiting.

### **3 Buccal cavity and administration**

- 3.1 The buccal area is the space between the inside of the cheek and the teeth, which is called the buccal cavity. Ideally, half the amount of Buccolam should be given into one side of the mouth, then the other half slowly into the other side.
- 3.2 The drug is quickly absorbed directly from the buccal cavity into the bloodstream to stop the seizure. If the Buccolam/Epistatus is incorrectly placed in the middle of the mouth it will not work as well because it cannot get into the bloodstream so quickly. Buccolam/Epistatus should not be swallowed, but if a small amount is inadvertently swallowed accidentally during the administration process, it will not cause any harm.

### **4 Joint epilepsy careplan (JEC)**

- 4.1 An individual JEC care plan is required for each person. This is because the dose and the point at which the medication should be administered during the seizure, will be different for each person.
- 4.2 The JEC should clearly state:
- The persons details.
  - The product and dose to be given.
  - When the Buccolam/Epistatus is to be given
  - Included on the authorisation form should be an indication of when an ambulance is to be summoned.
- 4.3 The JEC care plan must be updated annually or whenever there are any changes to the persons emergency rescue medication details.
- 4.4 Whenever emergency rescue medication (Rectal Diazepam or Buccal Midazolam) is being administered to a child for the first time in a school setting, a paramedic ambulance must always be summoned.

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## 5 Procedure for administering BUCCOLAM/EPISTATUS (Midazolam Oromucosal Solution)

- Two members of staff should be involved in this procedure.
- Check that the persons details match the pharmacy label on the medication and on the authorisation form and ensure it is the correct medication and dose for the individual person.
- Check that the medication is within the expiry date.
- Check at what stage in the seizure it should be given (e.g. after 5 mins).
- Break the tamper-proof seal and remove the oral syringe from the protective plastic tube.
- Put on latex free gloves (this is optional).
- **Remove and throw away the oral syringe cap before use, to avoid choking.**
- Explain to the person what is going to happen.
- Wipe away any excess saliva.
- Part the persons lips and carefully insert the tip of the oral syringe into the buccal area of the persons mouth, between the cheek and the gum of the lower jaw by the back teeth. Slowly drip the Buccolam/Epistatus solution into this area until the oral syringe is empty.
- If the persons teeth are clenched together they do not need to be parted.
- Remove the oral syringe from the persons mouth.
- It is not a problem if a small amount of medication is swallowed.

*Ensure the persons privacy and dignity is maintained as much as possible at all times.*

*Do not leave the person unattended until he/she has fully recovered. Two adults must be present during the procedure to check the medication and its administration.*

## 6 Disposal

- 6.1 After administering the Buccolam®/Epistatus it is advisable to keep the used oral syringe until the person has **fully** recovered. Ambulance staff may wish to check which medication has been given. Once checked the used oral syringe can be disposed of in a closed waste bin.

## 7 Storage

- 7.1 Buccolam/Epistatus should be stored at room temperature (not in a refrigerator) and not exposed to strong sunlight.

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- 7.2 Buccolam/Epistatus should be kept in its original container and be clearly labelled with the persons name. The Buccolam/Epistatus should be kept as part of a kit and stored in an accessible place **but must be out of reach of children**. The kit should comprise of:
- A JEC care plan signed by the persons Clinician or Epilepsy Specialist Nurse.
  - Buccolam/Epistatus oral syringe in its sealed protective plastic tube.
  - Latex free disposable gloves.
  - Paper tissues.

## 8 Recording

- 8.1 After administering the Buccolam/Epistatus it is important to record that you have done so. Administration of the medication should be recorded in the back of the JEC care plan, and include details of medication given, the dose given, the route of administration, the date and time it was given and by whom.
- 8.2 The incident should also be recorded, including a description of the seizure, duration and action taken. Information about what happened to the person following the administration of the Buccolam/Epistatus should also be included.

## 9 Reporting

- 9.1 The administration of Buccolam/Epistatus medication should be reported to the parents/carers as soon as possible (as indicated on the yellow epilepsy alert card).

## 10 Carrying the Buccolam®/Epistatus kit e.g. on day trips/day centre

- 10.1 When out, the Buccolam/Epistatus should be kept as part of a kit with the appropriate equipment and paperwork and should always be looked after by the member of staff who has responsibility for administering it (should it be required). It must never be left unattended.

## 11 Training

- 11.1 **Unqualified** staff who administer Buccolam/Epistatus (emergency rescue medication) must receive appropriate training , from a qualified health care professional e.g. Epilepsy Specialist Nurse, CYPN (Children and Young people's Nurse) prior to administration
- 12.2 Training must be updated **every 2 years**.

## 13.0 AUTHORISATION FORM/JEC

- 13.1 The JEC care plan must be updated annually or whenever there are any changes to the child's emergency rescue medication details.
- 13.2 Its continued prescription and use should be reviewed annually and should be withdrawn if no longer indicated.

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