

**DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
(JAPC)**

The management of emergency rescue medication (buccal/oro-mucosal midazolam) for children, young people and adults with prolonged or repeated generalised, convulsive (tonic-clonic, tonic or clonic) seizures in the community

JAPC has classified buccal midazolam preparations as:
Buccolam GREEN after specialist initiation (preferred brand)
Epistatus GREY

Where appropriate specialists should review existing patients and switched to the recommended Buccolam preparation. *Do not stop abruptly* without patient receiving training for Buccolam and an updated care plan.

To reflect out of area prescribing and due to clinical concerns and risks, Epistatus is re-classified from DNP to Grey for when initiated by out of Derbyshire provider. In these circumstances it will be at the discretion of the prescribing clinician (includes primary care clinicians who continue prescribing) to switch to Buccolam with patient and/or carer training and updated care plan, or to continue prescribing Epistatus.

Prescribe by brand to ensure patient receive correct preparation/ strength

Be aware of the volume difference for the 2 products when switching – Buccolam is 10mg/2ml prefilled syringe, whereas Epistatus is 10mg/1ml prefilled syringe.

Introduction

With the emphasis on community care increasingly lay carers are being asked to respond to prolonged convulsive seizures that have the potential to develop into status epilepticus.

Most epileptic seizures stop of their own accord and do not need medical attention. Status epilepticus is a condition characterised by seizure or a series of seizures that last for 30 minutes or more, without the person regaining consciousness. If a seizure continues for more than 5 minutes, it may not stop and could potentially develop into status epilepticus unless rapid treatment is given.

Status epilepticus can occur in any type of seizure. When status epilepticus occurs in convulsive seizures it is a medical emergency and needs urgent treatment.

Buccal midazolam should be considered for immediate emergency care and treatment in children, young people and adults who have prolonged (lasting 5 minutes or more) or repeated (three or more in an hour) convulsive seizures in the community.

Buccal Midazolam

	Buccolam® (licensed in children 3months to <18years)
Formulary status	GREEN after specialist initiation for children under 18 years and adults
Ingredient	midazolam hydrochloride
Form/ strength	5mg/mL pre-filled oral syringes of 2.5mg, 5mg, 7.5mg, 10mg
Dose- buccal administration (BNFc)	<u>Neonates to 3mths</u> : 300microgram/kg (max. 2.5mg) unlicensed <u>3mths-11months</u> : 2.5mg (depending on the weight of the child, smaller doses may be needed at 300microgram/kg, max.2.5mg) <u>1-4yrs</u> : 5mg <u>5-9yrs</u> : 7.5mg <u>10-17yrs</u> : 10mg <u>Adult 18yrs and over</u> : 10mg (unlicensed)

The management of emergency rescue medication for children, young people and adults with prolonged or repeated generalised, convulsive seizures in the community.

- It is recognised that the administration of Buccal Midazolam for the control of prolonged or continuous seizures is an effective treatment which can be lifesaving. Given promptly this relatively simple procedure can prevent major disruption to daily life resulting from hospital emergency treatment and therefore is being increasingly used as an emergency treatment for prolonged convulsive seizures.
- Midazolam is a water-soluble, short-acting, benzodiazepine and can be easily administered into the buccal cavity (between the lower gums and cheeks). It is available as an oro-mucosal solution in prefilled syringes.
- Buccolam® is a licensed product for the treatment of prolonged acute seizures in children and young people up to the age of eighteen, its use in adults is as yet unlicensed.
- The MHRA has stipulated that licensed products should be used wherever possible, even if it means using a product off-label and outside its licensed indications.
- Doses for children and young people should be advised by the Children's Specialist Epilepsy services. Adults should normally be prescribed 10mg.
- JAPC recognising that it may not be practical due to formulary differences to refer to a specialist outside of Derbyshire for a patient already initiated on Epistatus. In these circumstances it will be at the discretion of the prescribing clinician to switch to Buccolam with patient and/or carer training and updated care plans, or to continue prescribing Epistatus. Prescribers are reminded of the importance that in order to switch to Buccolam patients and their carers need to be trained and or educated on the new product. Care plans should be updated at next review with specialist. Prescribers are reminded to be aware of the volume difference for the 2 products when switching – Buccolam is 10mg/2ml prefilled syringe, whereas Epistatus is 10mg/1ml prefilled syringe.

Prescribing and monitoring: children and young adults

- All children and young adults must be seen by Children's Epilepsy Specialist services for all seizure management and before rescue medication is prescribed.
- Buccal midazolam should only be considered for use in the community for children who have had a previous episode of prolonged (over 5 minutes) or serial convulsive seizures.
- Buccal midazolam should be used as first-line treatment in children with prolonged or repeated seizures in the community. Only prescribe rectal diazepam if preferred or if buccal midazolam is not available.
- Consider discontinuation if no history of prolonged or repeated generalised, convulsive (tonic-clonic, tonic or clonic) within the last two years.
- Following an emergency acute admission ensure a referral has been made by the Emergency Department to Specialist Children's Epilepsy services for an appropriate review.

Prescribing and monitoring: adults

- Consider referring to neurology services when buccal midazolam is being considered for use in the community for prolonged or serial convulsive seizures.
- Buccal midazolam should only be considered for use in the community for adults who have had a previous episode of prolonged (over 5 minutes) or serial convulsive seizures.
- Administer buccal midazolam as first-line treatment in adults with prolonged or repeated seizures in the community. Only prescribe rectal diazepam if preferred or if buccal midazolam is not available.
- If currently prescribed rectal diazepam consider referral to neurology services for advice regarding switching to buccal midazolam.
- Consider discontinuation if no history of prolonged or repeated generalised, convulsive (tonic-clonic, tonic or clonic) within the last two years.
- Following an emergency acute admission ensure a referral has been by the Emergency Department to Neurology Services for an appropriate review.

Individual epilepsy management plan/emergency epilepsy plan

- All prescriptions of rescue medication should be supported with an individual plan (for example see Appendix 1).
- For children's Buccolam care proforma- see Children's Epilepsy Workstream in Trent (CEWT) Patient Information- Buccolam <http://www.cewt.org.uk/CEWT/Epilepsy-to-go.html>
- It is the prescriber's responsibility to ensure a management plan is completed and reviewed in conjunction with the individual's annual epilepsy review.
- Individual care plans should include the following information:
 - Name of child/adult
 - Warnings/triggers
 - Seizure classification and description
 - Usual duration of a seizure
 - Emergency medication treatment plan (prescribed medication, when to give it, initial dose, and usual reaction)
 - Difficulties in administration
 - If a second dose be given
 - When to call 999 for an emergency
 - Recovery and interventions
 - Prescriber's or health professionals signature.
- Administration of buccal midazolam should be administered by trained clinical personnel or, if specified by an individually agreed protocol drawn up with the specialist, by family members or carers with appropriate training. **The prescriber should ensure family members or carers are trained or have access to appropriate training which should include epilepsy awareness, administration of buccal midazolam and health and safety issues.**

A training video produced by Takeda is available at <https://vimeo.com/299456109> and is accessible by using the password 'Buccolam0030'.

Key Contacts

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Consultee

Rachael Wheway, Children's Epilepsy Nurse Derbyshire Children's Hospital
Derbyshire Medicines Management Guidelines and Shared Care Group

References

Epilepsy Nurses Association (ESNA) (June 2019)

<https://www.esna-online.org/wp-content/uploads/2018/12/June-2019-Midazolam-guidelines.pdf>

NICE NG217 Epilepsies in children, young people and adults

Children's Epilepsy Workstream in Trent (CEWT) Patient Information Buccolam

<http://www.cewt.org.uk/CEWT/Epilepsy-to-go.html>

Document Control	Date

Appendix 1: Example epilepsy management plan/emergency epilepsy plan

Appendix 1

Example of Buccal Midazolam Care Plan

Name	
Date of birth	Known allergies
Description of seizures which may require buccal midazolam	
1.....	
.....	
.....	
Usual duration of seizure	
2.....	
.....	
.....	
Usual duration of seizure	
3.....	
.....	
.....	
Usual duration of seizure	
4.....	
.....	
.....	
Usual duration of seizure	
5.....	
.....	
.....	
Other useful information	
6.....	
.....	
.....	

Midazolam treatment plan

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-disciplinary 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.

6. When should 999 be dialled 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

All occasions when buccal midazolam is administered must be recorded

This plan has been agreed by the following:

Prescriber/epilepsy specialist

Signature:

Date:

Patient/ patient's representative (note below):

Signature:

Date:

Care plan author:

Signature:

Date:

NB Patient's representative e.g. responsible family member or care manager.