

ADMINISTRATION OF EPISTATUS® BUCCAL MIDAZOLAM - 10MG (BASE) IN 1ML SUGAR-FREE SYRUP TO PEOPLE WHO HAVE EPILEPSY

Purpose:

To provide Colchester PCT Learning Disabilities Service employee's with the practical skills to administer Epistatus® buccal midazolam. This protocol is also available to other agencies and professionals/individuals

Responsibility:

All employees of Colchester PCT Learning Disabilities Service who may be asked to administer Epistatus® buccal midazolam. This protocol is also available to other agencies and professionals/individuals

Definition:

Protocol

Background

Midazolam is a short-acting benzodiazepine. Epistatus® buccal midazolam is used in the treatment of potentially life threatening tonic-clonic seizures, which are likely to progress to status epilepticus, as an alternative to rectal administration of diazepam.

Epistatus® buccal midazolam may also be used for the treatment of

prolonged partial seizures. However Amsed® Midazolam Oral liquid (2.5mg in 1ml) is available for the treatment of all types of partial seizures. Amsed® can also be used to control non-life threatening clusters of any type of epileptic seizure

Epistatus® buccal midazolam is usually prescribed as “as required” (PRN) medication for emergency treatment and is prescribed on a named patient only basis.

This protocol should be read in conjunction with Colchester PCT Learning Disability Services “*Policy guidelines and standards for Colchester PCT Learning Disability Services employees providing training in epilepsy awareness and the administration of buccal midazolam in the treatment of recurrent or prolonged seizures in people with epilepsy*”.

The person administering the Epistatus® buccal midazolam should be requested to complete an assessment form between March 2005 and December 2005. *Appendix 1*

NOTE: A Primary care giver has the right to refuse to do this. They may wish to answer the questions verbally with the professional monitoring the epilepsy.

Aim

To enable carers and professionals to have basic knowledge and understanding of epilepsy seizure management.

To enable carers and professionals to administer Epistatus® buccal

midazolam in a safe and effective manner for the emergency treatment for seizures.

Requirement:

An individual seizure management plan will be in place.

The individual, their next of kin, carers (as appropriate) will be made aware that Epistatus® (buccal midazolam) is not licensed as a medication for the control of epilepsy.

The patient information leaflet from the Epistatus® pack will be given to the individual and carer and discussed with them.

All potential carers of individuals who require emergency Epistatus® buccal midazolam must have undertaken, and satisfactorily completed:

- ▼ Epilepsy Awareness Training (within the previous two years) facilitated by a nurse employed by the Learning Disabilities Service, Colchester Primary Care Trust or another professional agreed by them i.e. specialist task health care coordinator
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- ▼ Epistatus® buccal midazolam training facilitated by a nurse employed by the Learning Disabilities Service, Colchester Primary Care Trust or another professional agreed by them i.e. specialist task health care coordinator

Prescription:

Buccal midazolam is prescribed on a named patient basis only.

Midazolam will be prescribed or advised to be prescribed by a consultant neurologist, consultant psychiatrist, SPR, pediatrician or GP involved in the individual's epilepsy management.

The prescription will only be written when all potential administrators of Epistatus® (buccal midazolam) have been trained in its use and the individual seizure management plan has been completed in conjunction with and signed by the prescribing medical practitioner.

Consider

▼ Contraindications and Precautions

Contraindications include hypersensitivity to midazolam or diazepam and acute narrow angle glaucoma.

The safety of Midazolam in pregnancy has not been established.

▼ Interactions

Simultaneous use of Erythromycin or cimetidine with Epistatus ® buccal midazolam may result in excessive drowsiness.

Individual seizure management plan:

(The guidelines below are based on JEC care plan guidelines for the administration of rectal diazepam).

An individual seizure management plan for each person will need to be drawn up in conjunction with and signed by the prescribing

medical practitioner with specific guidelines for administration, including:

- ▼ Name of individual
- ▼ Seizure classification / description
- ▼ Possible seizure triggers
- ▼ Possible seizure warning signs
- ▼ Usual duration of seizure
- ▼ Usual recovery from seizure
- ▼ When Epistatus® buccal midazolam should be administered
- ▼ How much is to be given
- ▼ What the usual reaction is
- ▼ Whether a repeated dose can be given
- ▼ Time interval for a repeat administration
- ▼ Maximum amount of Epistatus® buccal midazolam in a 24-hour period
- ▼ When Epistatus® buccal midazolam should not be administered
- ▼ When emergency services should be contact
- ▼ Other people to be contacted (if appropriate)

The seizure management plan should have an expiry date of no longer than six months, to ensure it is reviewed.

Guidelines on when to administer Epistatus® buccal midazolam can be seen in appendix 2.

EPISTATUS® BUCCAL MIDAZOLAM**ASSESSMENT DATA FORM MARCH 2005 to DECEMBER 2005****Introduction**

Midazolam is a benzodiazepine similar to Diazepam, which has been used for decades as a premedication before operations, dental treatment and other procedures. It is short-acting, and it will cause sedation, relaxation, and amnesia. During the last five years it has also been used orally for the emergency treatment of prolonged tonic-clonic seizures, as an alternative to rectal diazepam. This, as yet, an unlicensed use, but there is good evidence to support its use, and "Epistatus®" is an oral preparation which is manufactured specifically for this purpose. A patient information leaflet is provided with the pack. The product has only recently been used in this locality, and we would appreciate your feedback on your experience with it. Could you please complete this form each time you use "Epistatus®", and give the completed forms to your hospital Doctor or your community nurse?

Patient's initials	Male/female*	Age	Consultant	GP
Address*	At home	Care home	Hospital ward	Other
Date used	Time	Dose* 10mg 20mg	No. of doses this episode	
Response to Treatment Time to onset of actionminutes Duration of effecthours How sedating?* Not very 1 2 3 4 5 Very			Side effects	
Outcome* Seizure controlled Doctor called Hospital admission Other				
Other comments				
Comparison to rectal diazepam				
Onset was* quicker slower		Adverse effects/after effects were*		less more
Duration was* shorter longer		Ease of use*		easier harder
Initials of carer or person completing this form				

Please delete the words after the star if they do not apply

This information is confidential. Do not use the patient's full name or details.

Data is to be collated by Shelley Anderton, Community Learning Disabilities Nurse, Health House, Grange Way, Colchester CO2 8GU Tel. 01206 74 7756 Please contact Shelley for further information.

Ref: LD Buccal Midazolam assessment form April 04 Judith Woolley Pharmacist for Mental Health and Learning Disabilities, North Essex Tel. 01245 513239/41

GUIDELINES FOR WHEN EPISTATUS® BUCCAL MIDAZOLAM SHOULD BE ADMINISTERED TO A PERSON WITH EPILEPSY:

Firstly Consider:

Rectal Diazepam:

In certain circumstances, until carers feel comfortable with the administration of Epistatus® buccal midazolam, rectal diazepam may still need to be accessible (with appropriate seizure management plan in place) until it is clear that Epistatus® buccal midazolam is effective for the individual. This is extremely important in the case of individuals who have prolonged tonic-clonic seizures. If Epistatus® is not effective it may be that the Epistatus® has been administered incorrectly.

When to administer Epistatus® buccal midazolam:

It is important to have a clear understanding of what the usual pattern of seizure for each individual is. However, Epistatus (buccal midazolam) may be administered for the following reasons:

- One **tonic-clonic** seizure immediately follows another with no recovery in between;
- When a **tonic-clonic** seizure lasts five minutes; as the majority (75%) of seizures will expire within five minutes and buccal midazolam may cause severe drowsiness.

- If it is known that the individual's seizures always last more than 5 minutes, then the prescribing medical practitioner may advise that Epistatus® buccal midazolam should be administered immediately the tonic-clonic seizures occurs.
- The **tonic-clonic** lasts two minutes longer than is usual for the individual
- Three **tonic-clonic** seizures experienced within a one-hour period.
- Prolonged **simple partial** seizure or simple partial status epilepticus is not an emergency and usually does not require emergency treatment. However, each seizure management plan is individual and should take into account the impact on the individual's quality of life.
- Prolonged **complex partial** seizures or complex partial status epilepticus are not usually a medical emergency. However, it will depend on the individual circumstances as to when Epistatus® (buccal midazolam) should be administered: consider the impact of the seizure, potential injury to self and others, impact on the individual's quality of life. Bear in mind the fact that Epistatus® buccal midazolam may also impair the individual's quality of life as they may be drowsy for several hours following administration. However if a complex partial seizure continues for more than 30 minutes Epistatus® (buccal midazolam) may need to be given.

Administering the first dose:

A single dose of Epistatus® 10mg (base) in 1ml sugar-free syrup should be effective in stopping the seizure for the majority of adult's individuals. It may protect the individual from recurring seizures for up to four hours.

Administering a second dose:

A 2ND dose is not recommended within 6 hours of the first dose. However, in exceptional circumstances it may be that an identified individual will require a further dose if there has been no effect from the first dose 10 minutes after its administration.

Calling an ambulance:

If there are concerns about overdose or undesirable side effects which may be manifested by one or more of the following:

- Excessive sleepiness, confusion, low blood pressure, shallow breathing and excitation

For first time users or individuals transferring to Epistatus® buccal midazolam who have infrequently received emergency medication such as rectal diazepam for their seizures until experience indicates otherwise, it may be advisable to call an ambulance as a precautionary measure.

For individuals known to suffer tonic-clonic seizures that are usually prolonged, Epistatus® buccal midazolam should be given immediately or even at the first indicative signs of seizure onset. For

those individuals, until experience indicates otherwise, it may be advisable to call an ambulance without delay.

If the seizure has not terminated within 10 minutes of administration (as Initial effects become apparent after approximately 5 minutes and about 80% of seizures are terminated within 10 minutes).

If there are any concerns about the individual's well-being

Maximum dose in a 24-hour period

It is advised that no more than 20mg Epistatus® buccal midazolam is given in a twenty-four hour period: However, in exceptional circumstances it may be that identified adult individuals will require more than this.

Protocol written by:

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In consultation with:

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Acknowledgement:

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