

Epistatus® Midazolam Buccal Liquid 10mg/ml

Shared Care Guidelines for adults and children:

Shared Care Guidelines: Use of buccal midazolam as an intervention for prolonged seizures and prevention of Status Epilepticus

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines ways in which the responsibilities for managing the prescribing of midazolam for adult patients and children prone to prolonged generalised seizures (lasting longer than 5 minutes) or serial seizures, can be shared between the specialist and the general practitioner (GP). GPs are invited to participate but if the GP is not confident to undertake these roles, they are under no obligation to do so. In such an event, the clinical responsibility for the patient in respect of this diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP, patient and their carers. The intention to share care should be explained to the patient and their carers by the specialist initiating treatment. It is important that it is explained that Epistatus® does not currently have a product licence for the treatment of prolonged epileptic seizures (although the manufacturer is currently pursuing a licence which is expected by the end of 2014) and that both patients and carers are consulted and in agreement with this treatment.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Initiate treatment and provide at least 4 doses i.e. Midazolam 10mg in 1ml sugar free liquid in a 5ml bottle with 4 x 1ml oral syringes providing 4 x 1ml doses. Prescribe by the brand name "Epistatus®".
2	Discuss the benefits and side effects of treatment with the patient and consider the use of unlicensed medicines and only use when the benefits outweigh the risks. The prescriber must make every effort to obtain consent to treatment and inform the patient and carer of the medicine's licence status and that the effects of an unlicensed product will be less well understood than those of a licensed product.
3	Ensure that the patient/carer understands when and how to give the medication (An identified member of the specialist team, such as learning disabilities nurse or epilepsy specialist nurse, will work with the patient and carer to develop a protocol for administration, train in use, ensure appropriate storage and provide written/verbal advice in a way that the individuals can understand). Also ensure that the patient & carer understands when to visit their GP and when to call for an ambulance.
4	Ask the GP whether they are willing to participate in shared care.
5	Supply the GP with background information about diagnosis, the reasons for selecting midazolam and details of how to prescribe it, including details of how often doses can be repeated, maximum dose in 24 hours and details of any combination therapy. Also, when to refer back to the specialist & when to call for an ambulance. This summary should be received within 14 days of a hospital outpatient review or in-patient stay.
6	Review the patient's condition and monitor response to treatment regularly (at least 6 monthly).
7	Advise GP on when to stop, alter or change treatment.
8	Report adverse events to the MHRA.
9	Ensure clear arrangements for GP and carer back-up, advice and support.

General Practitioner responsibilities	
1.	Reply to the request for shared care as soon as practicable.
2.	Prescribe midazolam after communication with specialist about need for treatment, the formulation to be used and the dose recommended.
3.	Refer promptly to specialist if frequency of use increases, lack of clinical efficacy is suspected or any concerns arise.
4.	Report to and seek advice from specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
5.	Stop treatment on the advice of the specialist.
6.	Report adverse events to the specialist and MHRA

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Patient's role	
<ol style="list-style-type: none"> 1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment. 2. Share any concerns in relation to treatment with the medicine. 3. Report any adverse effects to the specialist or GP whilst taking the medicine. 	

MEDICATION DETAILS

Indication	<p>Prolonged or serial convulsive seizures (convulsive seizures lasting more than 5 minutes or two without recovery in between or three within an hour). Midazolam is a short acting benzodiazepine that offers an alternative to rectal diazepam</p>
Products available	<p>Midazolam buccal liquid is available as 2 different strength products, but due to safety issues we recommend the use of Epistatus® in Wiltshire & Swindon. Special products ltd make Epistatus® (01932 690325) under a 'specials' manufacturing licence. N.B. Midazolam buccal liquid is a Controlled Drug – schedule 3</p> <p>NHS Wiltshire and Salisbury NHS foundation trust recommend use of the unlicensed buccal 10mg in 1ml midazolam solution (Epistatus®) rather than the licensed buccal 5mg in 1ml midazolam solution (Buccolam®) because of local familiarity with the 10mg in 1ml strength. Epistatus® is expected to get an UK product licence by the end of 2014.</p>
Form	<p>Midazolam 10mg in 1ml sugar free liquid in a 5ml bottle with 4 x 1ml oral syringes providing 4 x 1ml doses. Single use prefille syringes are also available. Prescribe by the brand name "Epistatus®".</p>
Administration	<p>Draw up the prescribed dose into the oral syringe provided. Administer as a single dose into the buccal cavity (half in each side of mouth if large volume or small child).</p>
Dose and frequency	<p>The amount of midazolam buccal liquid used depends on weight and age. The usual doses are:</p> <ul style="list-style-type: none"> • Children under 6 months- the dose is based on weight (300micrograms per kilogram) • Children 6 months to 1 year 2.5mg (0.25ml) • Children 1 to 5 years 5mg (0.5ml) • Children 5 to 10 years 7.5mg(0.75ml) • Children over 10 years and adults 10mg (1ml) <p>If a response is not seen after a further 5 minutes, call for assistance.</p> <p>Do NOT give a second dose unless this has been previously agreed with the consultant and parent/carer. Where a second dose has been pre agreed, a second dose may be given 10 minutes later if no response is apparent and the patient is breathing normally. If the patients' breathing becomes shallow, call an ambulance and do not administer a second dose.</p> <p>What to do if a seizure starts again If there is a further seizure an ambulance should be called. Ambulance staff may repeat the dose if deemed appropriate. The official guidance states that no more doses should be given in the next 6 hours for children weighing 40kg or less or 12 hours for bigger children and adults (midazolam half life shorter in young children). Local opinion is that if the seizures stop but the patient experiences further seizures within the following 24 hours an ambulance should be called. The maximum recommended dose in 24 hours is 20mg. Please follow the advice given by the initiating specialist.</p>
Contra-indications	<p>Hypersensitivity to midazolam Pregnancy (safety has not been established) Acute narrow angle glaucoma</p>
Side effects	<p>The most common reported side effect is drowsiness; in some cases this may be severe. All patients receiving midazolam are likely to be drowsy for several hours after administration Rare-agitation, restlessness and disorientation have been reported Rare-respiratory depression</p>
Monitoring	<p>Prescribing frequency- if this increases and the patient has been having more seizures, refer back to the specialist for advice.</p>

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Drug interactions	Erythromycin, other macrolides and cimetidine inhibit the metabolism of midazolam. This may result in prolonged duration of sedative effect.
Storage	Do not store in a fridge as crystallisation may occur

BACK-UP ADVICE AND SUPPORT

Please note: out of hours please contact the oncall medical or paediatric team for emergency advice

Contact details	Telephone No.	Bleep:	Email address:
Dr Joanna Lovett Consultant Neurologist (adults)	Ext 3512		Joanna.lovett@salisbury.nhs.uk
Pharmacy Dispensary Manager	Ext 4268		
Dr Jim Baird Consultant Paediatrician	Ext 2311	Available through Switch Board	Jim.baird@salisbury.nhs.uk
Lou Pitman, Lead Pharmacist (Paediatrics)	Ext 4270		louise.pitman@salisbury.nhs.uk

References

Patient information-Epistatus® midazolam buccal liquid 10mg/ml. Special products limited.

www.specialproducts.biz

British Epilepsy Association. www.epilepsy.org.uk

BNF no 62 September 2011 www.bnf.org

Epilepsy in children and young people. NICE Oct 2004 www.nice.org

Eastern paediatric epilepsy network . www.networks.nhs.uk/nhs-networks/eastern-paediatrics-epilepsy-network

NPSA Signal February 2012 Prevention of harm with buccal midazolam

Document details

Prepared by Dr Rachel Hobson Formulary Pharmacist
 NHS Wiltshire December 2011.

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