

Nottinghamshire Health Community Guideline for the use of Buccal Midazolam (Epistatus®) in children and adults

Introduction

Buccal Midazolam 10mg/ml is an effective, more socially acceptable and well-tolerated alternative to Rectal Diazepam¹. GPs are supported in prescribing it to patients on the specific recommendation of a specialist.

NB This guideline relates specifically to the Epistatus® preparation.

Licenced Indication

Epistatus® is an *unlicensed* 'specials' preparation manufactured specifically for buccal management of epileptic seizures. It contains 10mg/ml midazolam formulated in a sugar free syrup and is supplied as a bottle containing 5ml with four oral 1ml syringes.

Place in therapy

These will be tailored to each patient but in general buccal midazolam is used as required for prolonged e.g. longer than 5 or 10 minutes, convulsive epileptic seizures. It is also used for a prolonged series of epileptic seizures continuing for 5 or 10 minutes or more without the patient waking up and coming round in between. Stopping an epileptic seizure promptly after 5 or 10 minutes with buccal midazolam is safe and effective and supported by NICE guidance¹. It is likely to reduce the chance of seizures becoming status epilepticus.

Dose

This will be tailored to each patient but in general doses between 0.3-0.5 mg/kg up to a maximum single dose of 10 mg are used in children and 10 mg doses are used in adults.

Age of patient	Dose of Epistatus (1 st and 2 nd doses)
Birth to 6 months	0.30mg/kg (0.03ml/kg)
6 to 12 months	2.5mg (0.25ml)
1 to 4 years	5mg (0.5ml)
5 to 9 years	7.5mg (0.75ml)
10 years and over	10mg (1ml)

NB Prescription by weight rather than age may be more appropriate for some children

Administration

The required dose is drawn up and administered by a trained parent or carer. The specialist prescriber, clinical nurse specialist, or trained community nurse will provide training, and a leaflet with the indications, details of administration, dose and other specific advice.

The first dose

This may need to be given in a community setting. If the patient has never been given buccal midazolam (or a similar nasal, buccal, or intravenous benzodiazepine) before, the parents or carers may have been advised to call the emergency services (Ambulance or Para-medic) once the dose is given in case of respiratory depression. There is no

evidence that respiratory depression is more or less common with buccal midazolam than with rectal diazepam². Parents and carers of patients at risk of prolonged convulsive epileptic seizures may also be trained in age appropriate Basic Life Support.

Repeated doses

In general a second dose is not often used in the community setting within a 24-hour period. Some individuals however may be advised that after initial recovery a further dose may be given 6 or more hours later if they have a second prolonged seizure. In clinical settings (e.g. medical facilities or hospitals) a second dose is given 10 minutes after the first if the seizure continues. Occasionally this might be advised in special circumstances in a community setting.

Contraindications

Acute narrow angle glaucoma
Known hypersensitivity

Side effects

Drowsiness (may persist for several hours after administration)
Agitation, restlessness and disorientation have been reported, although these are rare.

Costs

Community Pharmacies will have to order this in as a 'special' which may take some time. Typical costs per 5ml bottle £29.80 - £78.67 + VAT + handling/ carriage fee depending on the supplier (Prices obtained April 2008).

Legal category

On January 1st 2008, the legal classification for midazolam changed from a Schedule 4 CD (Controlled Drug) to a Schedule 3 CD. ***All prescriptions for midazolam must satisfy the prescription requirements to be valid and include details of the dose, form, strength, directions for use and total quantity (in both words and figures)***

References

1. NICE Guidance 20: The epilepsies: diagnosis and management of the epilepsies in children and young people in primary and secondary care. October 2004.
www.nice.org.uk
2. McIntyre J, Robertson S, Norris E, Appleton R, Whitehouse WP, Phillips B, Martland T, Berry K, Collier J, Smith S, Choonara I. Safety and efficacy of buccal midazolam versus rectal diazepam for emergency treatment of seizures in children: a randomised controlled trial. *Lancet* 2005; **366**:204-210.
3. Special Products Ltd Data Sheet for Epistatus®

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