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 Diazepam. GPs are supported in prescribing it to patients on the specific recommendation of a specialist.

NB This guideline relates specifically to the Epistatus® preparation.

Licensed 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 guidance. 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.

<table>
<thead>
<tr>
<th>Age of patient</th>
<th>Dose of Epistatus (1st and 2nd doses)</th>
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</thead>
<tbody>
<tr>
<td>Birth to 6 months</td>
<td>0.30mg/kg (0.03ml/kg)</td>
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<tr>
<td>6 to 12 months</td>
<td>2.5mg (0.25ml)</td>
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<tr>
<td>1 to 4 years</td>
<td>5mg (0.5ml)</td>
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<tr>
<td>5 to 9 years</td>
<td>7.5mg (0.75ml)</td>
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<tr>
<td>10 years and over</td>
<td>10mg (1ml)</td>
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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 diazepam. 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


3. Special Products Ltd Data Sheet for Epistatus®

Authors
Dr Colin Dunkley, Sherwood Forest Hospital NHS Trust
Dr William Whitehouse, Nottingham University Hospitals NHS Trust