BLMK Area Prescribing Committee Buccal Midazolam Prescribing Guidance

Published:
June 2022
Review date: June 2025

Aim: To inform healthcare professionals of the recommended buccal midazolam product to prescribe for use in prolonged seizures.

Prescribing:

- Buccolam® has been licensed for use in prolonged seizures in children since 2011. It contains the hydrochloride salt (10mg in 2ml) and is available in pre-filled syringes in four fixed doses of 2.5mg, 5mg, 7.5mg and 10mg.
- Although only licensed in children, MHRA guidance states that a licensed product used off label is preferable to an unlicensed product, therefore it is recommended that Buccolam® is used in adults.
- Unlicensed products often contain midazolam 10mg/ml whilst Buccolam is 10mg/2ml therefore brand prescribing is important to ensure continuity and prevent selection errors. See the Buccolam dosage recommendation below.

Dose	Age	Colour of packaging
2.5mg (in 0.5ml)	3 months to 11 months	Yellow
5mg (in 1ml)	1 year to 4 years	Blue
7.5mg (in 1.5ml)	5 years to 9 years	Purple
10mg (in 2ml)	10 years and over (unlicensed over 18 years)	Orange

- Consider a switch to licensed Buccolam®, for any patients currently prescribed Epistatus® pre-filled syringes, taking into account all implications of the change, including updating of any emergency seizure plans. Any switch would be on a case-by-case basis with careful review of the current dose and appropriate support on the use of Buccolam® pre-filled syringes.
- Prescribe by the brand name (Buccolam®) to minimise the risk of selection errors
- State dose in milligrams (mg) AND volume in millilitres (ml).

Counselling:

Counselling should include:

- How to administer
- Epistatus is twice the strength (10mg/mL) versus Buccolam (10mg/2mL)
- That Buccolam® syringes are pre-filled and designed for once only use. The total contents of the syringe should be given
- Advise the patient/carer to check that they always receive the same brand and strength of preparation. Different strengths of Buccolam® have different coloured packaging this can help the patient /carer check they have right product.

If it is being given to adult patients, they or their carers may be concerned that the packaging states it is for children only. This is because it is not licensed in adults (NB: 10mg is the normal adult dose)

Patients and / or carers should be given a copy of 'How to administer Buccolam®' (see attached document) before they receive the product for the first time. Prescribers and / or carers should ensure that everybody who may need to administer Buccolam® (e.g., school nurses, carers, day centres) are aware of how to administer it.

Midazolam Oromucosal solution: Mechanism to switch to Buccolam® for children

This is the recommended mechanism, for reviewing and switching, to convert patients who are children to the preferred licenced Buccolam® Oromucosal solution from other preparations.

The mechanism is intended to keep parents/carers informed as well as School Nurses and School Staff so they can support parents/carers in the change processes and minimise risk of errors that may increase clinical risk of seizures.

Notes:

- Midazolam Oromucosal solution preparations are legally classified as a Schedule 3 Controlled Drug (CD No Register Exempt Safe Custody)
- Preparations available are all 5mg in 1mL:
  - Buccolam 2.5mg/0.5ml Oromucosal solution pre-filled oral syringes
  - Buccolam 5mg/1ml Oromucosal solution pre-filled oral syringes
  - Buccolam 7.5mg/1.5ml Oromucosal solution pre-filled oral syringes
  - Buccolam 10mg/2ml Oromucosal solution pre-filled oral syringes