

## Transfer to licensed Buccal Midazolam 5mg/ml (Buccolam) oromucosal solution Guidance for Practitioners

Buccolam is a formulation of midazolam suitable for buccal administration<sup>1,2</sup>. It is licensed for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years)<sup>2</sup>.

Whilst Buccolam is only licensed for use in children, the CCG supports the use of this product in adults (off label) in preference to the unlicensed pharmaceutical special.

- **Buccolam comes in a range of prefilled syringes and doses that are suitable for children aged 3 months to <18 years<sup>1</sup>. There are four different syringe sizes (2.5 mg in 0.5 mL; 5 mg in 1 mL; 7.5 mg in 1.5 mL; and 10 mg in 2 mL), these are colour coded (see table below)**
- **Buccolam is half the strength of some other unlicensed preparations<sup>1</sup>. In the event of a prescription being written for the unlicensed preparation (10mg/1ml) the prescriber **MUST** be alerted to the fact that there is a licensed preparation available (5mg/1ml).**
- **For infants aged 3 to 6 months, treatment should only be in hospital, where monitoring is possible and resuscitation equipment is available<sup>1,2</sup>.**

### Dosage, prescribing, dispensing and administration guidance<sup>2</sup>

Age range	Dose	Label colour
3 to 6 months hospital setting	2.5mg	Yellow
> 6 months to < 1 year	2.5mg	Yellow
1 year to < 5 years	5 mg	Blue
5 years to < 10 years	7.5 mg	Purple
10 years to < 18 years	10 mg	Orange

To avoid the risk of confusion, it is recommended that Buccolam is prescribed by brand name.

Buccolam comes in pre-filled, ready-to-use, plastic, oral-dosing syringes. Each original pack contains 4 syringes. Pharmacists are asked to ensure that each oral syringe is labelled, as well as the outer packaging when dispensing. This is because the individual oral syringes may be stored in various locations (e.g. school and home) and also carried by the patient.

Buccolam is for oromucosal use<sup>2</sup>. The full amount of solution should be inserted slowly into the space between the gum and the cheek. If necessary (for larger volumes and/or smaller patients), approximately half the dose should be given slowly into one side of the mouth, then the other half given slowly into the other side<sup>2</sup>.

Buccolam contains the hydrochloride salt, whereas some other preparations contain the maleate salt of midazolam. Although there is some suggestion that the maleate salt may be better absorbed in the buccal cavity, there are adequate studies with midazolam hydrochloride to support the dosing schedule authorised for Buccolam<sup>1</sup>.

### **Other safety information<sup>1</sup>**

- Hypersensitivity to the midazolam, benzodiazepines, or to any of the excipients may occur.
- Midazolam should be used with caution in patients with chronic respiratory insufficiency because it may further depress respiration.
- Midazolam may accumulate in patients with chronic renal failure, or impaired hepatic or cardiac function and should therefore be used with caution in these individuals.
- The most common adverse reactions in clinical trials of buccal midazolam were sedation, somnolence, depressed levels of consciousness, respiratory depression, and nausea and vomiting.

Always consult the Summary of Product Characteristics<sup>2</sup> (SPC) for further information on contraindications and side effects etc.

### **Use of unlicensed formulations of buccal midazolam**

Where an unlicensed buccal midazolam formulation is prescribed in preference to the licensed formulation (i.e. Buccolam), informed consent must be obtained from the patient/parent/carer and the reason for prescribing the unlicensed formulation documented in the patients clinical notes.

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<sup>1</sup> Buccal midazolam (Buccolam): new authorised medicine for paediatric use—care needed when transferring from unlicensed formulations. MHRA Drug Safety Update; vol 5, issue 3 October 2011

<sup>2</sup> VIROPHARMA. Buccolam SPC accessed via [www.medicines.org](http://www.medicines.org) 10<sup>th</sup> November 2015