Buccolam® (Buccal Midazolam)

Please see the full Summary of Product Characteristics for more information.[1]

Background Information	**Buccolam®** is used in Barnsley for patients aged between 3 months and 18 years. Patients over 18 years of age are prescribed Epistatus® as an **'off- label' indication**. Epistatus® is licenced for patients between 10 and 18 years. **Please Note:** the two brands are **NOT** interchangeable. They are different concentrations so could result in administration of the wrong dose. • Please prescribe by **BRAND NAME** to reduce the risk of error **NICE Clinical Guideline CG137. Epilepsy. Published January 2012, Updated October 2019.**[2] The Clinical Guideline, produced by NICE, for the treatment of epilepsy describes the place in therapy of buccal midazolam. Buccal midazolam or rectal diazepam can be used in the community for children, young people and adults who have had a previous episode of prolonged or serial convulsive seizures. Administer buccal midazolam as first-line treatment, or rectal diazepam, if preferred or if buccal midazolam is not available. If intravenous access is already established and resuscitation facilities are available, administer intravenous lorazepam.
BNF Therapeutic class	Status Epilepticus
Indication	**Indication/Licensing information** • Buccolam® is licensed for the treatment of prolonged convulsive seizures in patients aged 3 months to less than 18 years. For infants between 3-6 months of age treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available.[1]
Dosage and administration	See table below Buccolam® is for oromucosal use. The full amount of solution should be inserted slowly into the space between the gum and the cheek. Laryngo-tracheal insertion should be avoided to prevent accidental aspiration of the solution. 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.

Age	Dosage	Comments
3-6 months **Hospital setting only**	2.5mg (0.5ml)	In infants less than 6 months buccal midazolam should only be used within a hospital and where equipment is available for resuscitation and monitoring of the patient due to an increased risk of respiratory depression.[3]
> 6 months - <12 months	2.5mg (0.5ml)	Available as Buccolam® pre-filled Syringe **2.5mg in 0.5ml. (Yellow label)**
1 year - < 5 years	5mg (1.0ml)	Available as Buccolam® pre-filled syringe **5mg in 1.0ml. (Blue label)**
5 years - <10 years	7.5mg (1.5ml)	Available as Buccolam® pre-filled syringe **7.5mg in 1.5ml (Purple label)**
10 years to <18 years	10mg (2.0ml)	Available as Buccolam® pre-filled syringe **10mg in 2.0ml (Orange label)**

	Carers should only administer a single dose of midazolam. If the seizure has not stopped within 10 minutes after administration of midazolam, emergency medical assistance must be sought and the empty syringe given to the healthcare professional to provide information on the dose received by the patient. In December 2017, the MHRA reported that in a small number of cases the translucent tip-cap from the Buccolam® oral syringe, has remained on the syringe tip when pulling the red cap off. Syringes are now checked by the manufacturer but syringes issued before this check was implemented may still be in circulation. If the translucent tip cap remains on the syringe tip it will prevent administration of Buccolam®, and may also present a potential choking hazard. If this occurs, the translucent tip cap needs to be removed manually. If the tip-cap is in the patient's mouth, the carer should not attempt to remove it. Instead, they should turn the patient onto their side (recovery position) and make sure they spit it out when they stop fitting.[5] See here for more information
Contraindications	**Contraindications** • Hypersensitivity to the active substance, benzodiazepines or to any of the excipients. • Myasthenia gravis • Severe respiratory insufficiency • Sleep apnoea syndrome • Severe hepatic impairment
Cautions	**Cautions** Midazolam should be used with caution in patients with chronic respiratory insufficiency because midazolam may further depress respiration. Midazolam should be used with caution in patients with chronic renal failure, impaired hepatic or cardiac function. Midazolam may accumulate in patients with chronic renal failure or impaired hepatic function whilst in patients with impaired cardiac function it may cause decreased clearance of midazolam. Debilitated patients are more prone to the central nervous system (CNS) effects of benzodiazepines and, therefore, lower doses may be required. Midazolam should be avoided in patients with a medical history of alcohol or drug abuse. Midazolam may cause anterograde amnesia.
Adverse Drug Reactions	The most common side effects with Buccolam (seen in 1/100 to 1/10) are sedation, somnolence, depressed levels of consciousness, respiratory depression and nausea and vomiting.
Monitoring	There are no baseline or routine monitoring requirements. Disease monitoring – The patient will be reviewed by the Specialist service at least annually. Patients also have access to Epilepsy specialist nurses as required.
Interactions	Midazolam is metabolized by CYP3A4. Inhibitors and inducers of CYP3A4 have the potential to respectively increase and decrease the plasma concentrations and, subsequently, the effects of midazolam thus requiring dose adjustments accordingly. Careful monitoring of the clinical effects and vital signs is recommended during the use of midazolam with a CYP3A4 inhibitor even after a single dose. (Refer to SPC for details of specific drugs: https://www.medicines.org.uk/emc/search?q=buccolam

Contact names and details

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References

1. Summary of Product Characteristics: Buccolam®. December 2011, Updated October 2019. Available at: https://www.medicines.org.uk/emc/search?q=buccolam Accessed <21.11.2019>
2. NICE Clinical Guideline CG137: Epilepsies: diagnosis and management. January 2012, Updated October 2019. Available at: https://www.nice.org.uk/guidance/cg137 Accessed <21.11.2019>
3. Buccolam product information, European Medicines Agency. Updated November 2019. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002267/human_med_001479.jsp&mid=WC0b01ac058001d124&murl=menus/medicines/medicines.jsp&jsenabled=true Accessed <21.11.2019>
4. Class 4 medicines defect information: Buccolam (midazolam) oromucosal prefilled syringes. Dec 2017. Available at https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-buccolam-midazolam-oromuscosal-solution-pre-filled-syringes. Accessed <21.11.2019>
5. Parents and carers advised to inspect Buccolam oral syringes before use. January 2018. Available at https://www.gov.uk/government/news/parents-and-carers-advised-to-inspect-buccolam-oral-syringes-before-use. Accessed <22.11.2019>

Development Process

This guidance was originally produced in liaison with Dr Iqbal (Lead Consultant for Paediatric Epilepsy) following an AMBER-G classification status of Buccolam® by the Barnsley Area Prescribing Committee in July 2012. This guideline has been updated and has been subject to consultation and endorsement by the Area Prescribing Committee on 14th October 2020.