BUCCOLAM® (midazolam) 2.5 mg, 5 mg, 7.5 mg & 10 mg oromucosal solution Prescribing Information Great Britain

Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Presentation: Pre-filled oral syringes containing midazolam (as hydrochloride) 2.5 mg in 0.5 ml solution, 5 mg in 1 ml solution, 7.5 mg in 1.5 ml solution and 10 mg in 2 ml solution for oromucosal use. **Indication:** ***(All strengths)*** Treatment of prolonged, acute, convulsive seizures in infants, toddlers, children, and adolescents (from 3 months to <18 years). BUCCOLAM must only be used by parents/carers where the patient has been diagnosed to have epilepsy. For infants between 3–6 months of age treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available. (***10 mg only)*** Treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and infants aged 3 months and above. **Dosage and administration:** BUCCOLAM is for oromucosal use. 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. Standard doses are indicated below:

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

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. A second or repeat dose when seizures re-occur after an initial response should not be given without prior medical advice. The oral syringe cap should be removed before use to avoid risk of choking. **For detailed instructions on how to administer the medicinal product please refer to SmPC.** *Children under 3 months:* Not indicated. The safety and efficacy in children aged 0–3 months has not been established. *Patients with renal impairment:* No dose adjustment is required. No efficacy studies of midazolam in patients with chronic renal failure have been reported, therefore BUCCOLAM should be used with caution in patients with chronic renal failure as elimination of midazolam may be delayed and the effects prolonged. *Patients with hepatic impairment:* Hepatic impairment reduces the clearance of midazolam with a subsequent increase in terminal half-life. Careful monitoring of clinical effects and vital signs is recommended. Not to be used in patients with severe hepatic impairment. **Contraindications:** Hypersensitivity to the active substance, benzodiazepine or to any of the excipients. Patients suffering from myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome and severe hepatic impairment. **Warnings and precautions:** *Respiratory insufficiency:* Midazolam should be used with caution in patients with chronic respiratory insufficiency because midazolam may further depress respiration. *Paediatric patients 3 to 6 months of age:* Delayed respiratory depression due high active metabolite concentrations in the 3–6 months age group cannot be excluded. The use of BUCCOLAM in this age group should be limited for use only under the supervision of a healthcare professional where resuscitation equipment is available. *Altered elimination:* Midazolam should be used with caution in elderly patients and 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. *Concomitant use with other benzodiazepines:* Debilitated patients are more prone to the central nervous system effects of benzodiazepines and, therefore, lower doses may be required. *History of alcohol or drug abuse:* Midazolam should be avoided in patients with a medical history of alcohol or drug abuse. *Amnesia:* May cause anterograde amnesia. **Interactions:** Midazolam is metabolised by CYP3A4. Medicinal products that inhibit or induce CYP3A4 have the potential to respectively increase and decrease the plasma concentrations of midazolam and, subsequently, the effects of midazolam, thus requiring dose adjustments accordingly. Pharmacokinetic interactions with CYP3A4 inhibitors or inducers are more pronounced for oral as compared to oromucosal or parenteral midazolam as CYP3A4 enzymes are also present in the upper gastrointestinal tract. Careful monitoring of clinical effects and vital signs is recommended during the use of midazolam with a CYP3A4 inhibitor even after a single dose. Concomitant use of the following mediation should be undertaken with caution: Fentanyl; antiepileptics; calcium-channel blockers; dopaminergic agents; muscle relaxants; nabilone; ulcer-healing medicinal products; xanthines; grapefruit juice; azole antifungals; macrolide antibiotics; HIV protease inhibitors; atorvastatin; rifampicin; St John's Wort and sedative/hypnotic products and CNS depressants including alcohol. Alcohol intake should be strongly avoided in case of midazolam administration. **For further information please refer to SmPC. Pregnancy and lactation:** Midazolam may be used during pregnancy if clearly necessary. The risk for newborn infants should be considered in the event of administration of midazolam in the third trimester of pregnancy. *Breast Feeding*: Midazolam passes in low quantities (0.6%) into breast milk and therefore it may not be necessary to stop breastfeeding following a single dose of midazolam. **Effects on ability to drive and use machines**: Midazolam has a major influence on the ability to drive and use machines. Sedation, amnesia, impaired attention and impaired muscular function may adversely affect the ability to drive, ride a bicycle or use machines. After receiving midazolam, the patient should be warned not to drive a vehicle or operate a machine until completely recovered. **Undesirable effects:** *Common* (≥1/100 to <1/10): sedation, somnolence, depressed levels of consciousness, respiratory depression, nausea and vomiting. *Other serious undesirable effects:* angioedema and anaphylactic reaction. **Please refer to SmPC for full details. Legal category:** POM. **Presentation & cost:** Pack of 4 oral syringes: 2.5 mg - £82.00, 5 mg - £85.50, 7.5 mg - £89.00, 10 mg - £91.50. **Marketing authorisation numbers:** PLGB 16869/0017-0020;. For further information please contact Neuraxpharm UK Ltd, Suite 2, Arlington Flex, Third Floor, Building 1420, Arlington Business Park, Theale, Reading, Berkshire, RG7 4SA **Date of preparation:** October 2024

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions. UK reporting forms and information can be found via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Neuraxpharm UK Ltd by emailing pv-uk@neuraxpharm.com