

Glycopyrronium Bromide 1 mg/5 ml Oral Solution

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

Product name: Glycopyrronium Bromide 1 mg/5 ml Oral Solution **Composition:** Each 5 ml of oral solution contains 1 mg of glycopyrronium bromide

Legal category: Prescription Only Medicine

Indications: For use in children and adolescents aged 3 years and older with chronic neurological disorders as symptomatic treatment of severe sialorrhoea (chronic pathological drooling).

Dosage and administration: High fat foods reduce oral bioavailability. Hence, take Glycopyrronium Bromide one hour before or two hours after meals. Dose should be adjusted to achieve optimal symptomatic control with minimal adverse effects. For oral use and use via nasogastric & PEG feeding tubes. Dosing is based on the weight of the child. Using the graduated syringe provided, initiate dosing at 0.02 mg/kg three times daily and titrate in increments of 0.02 mg/kg every 5-7 days based on therapeutic response and adverse reactions. The maximum recommended dosage is 0.1 mg/kg three times daily not exceeding 1.5-3 mg per dose based on weight. Please refer to dosing table (Table 1) in full Summary of Product Characteristics.

Product is not recommended in children younger than 3 years. **Contraindications:** hypersensitivity to glycopyrronium bromide or excipients. Angle-closure glaucoma; myasthenia gravis; pyloric stenosis; paralytic ileus; intestinal obstruction; prostatic enlargement; urinary retention; severe renal impairment (eGFR < 30 ml/min/1.73 m²); pregnancy & breastfeeding; potassium chloride solid oral products; other anticholinergic drugs.

Warnings and precautions: Use with caution in the elderly; gastro-oesophageal reflux disease; ulcerative colitis; pre-existing constipation; acute myocardial infarction; hypertension; tachycardia (including hyperthyroidism; cardiac insufficiency, cardiac surgery); coronary artery disease; cardiac arrhythmias, including use of inhalation anaesthesia. Diarrhoea may be an early symptom of incomplete intestinal obstruction, especially in patients with

ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful. Glycopyrronium bromide can inhibit sweating, patients with increased temperature should be observed closely. In high environmental temperature, heat prostration can occur with use of glycopyrronium bromide. Avoid repeated or large doses of glycopyrronium bromide in patients with uraemia. Patients with fructose intolerance should not take this medicine due to presence of sorbitol. No safety data beyond 24 weeks. Treatment should be kept as short as possible.

Drug interactions: combinations with other anticholinergic drugs may add to adverse effects (e.g. tricyclic antidepressants, antihistamines, monoamine oxidase inhibitors, phenothiazines, etc). Combinations with corticosteroids may result in increased intraocular pressure. Domperidone, metoclopramide, levodopa, haloperidol; nitrates; topiramate, zonisamide; inhaled anaesthetics. Concurrent use with slow-dissolving tablets of digoxin, atenolol or metformin may result in increased serum levels of these medicines. **Adverse effects:** dry mouth, constipation, diarrhoea, vomiting, nasal congestion, behavioural changes, urinary urgency and retention, pyrexia, flushing. Less frequent side effects include worsening of pre-existing seizures; confusion (particularly in the elderly); angle-closure glaucoma. Please consult full Summary of Product Characteristics for other adverse effects.

NHS price: £91.00 per 150 ml bottle

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Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Clinigen at: E-mail: drugsafety@clinigengroup.com Fax number: +44(0)1932 824284