Prescribing Information (UK)

Sialanar (400 micrograms/ml glycopyrronium bromide) oral solution. Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

Active Ingredient: 1ml contains 400 micrograms glycopyrronium bromide, equivalent to 320 micrograms glycopyrronium. **Indication:** Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) due to chronic neurological disorders of childhood-onset in patients aged 3 years and older. **Dosage**: ***Paediatric population (3 years and older):*** Start with approximately 16 mcg/kg body weight of glycopyrronium bromide per dose, three times per day. Increase dose weekly as per SmPC until efficacy is balanced with undesirable effects. Titrate to maximum individual dose of 80 mcg/kg body weight glycopyrronium bromide or 6ml three times a day, whichever is less. ***Adult population:*** For adolescents with chronic neurological disorders of childhood-onset, their stable dose of Sialanar can be continued into adulthood. For adults with chronic neurological disorders of childhood-onset initiating Sialanar for the first time, refer to the SmPC for the dosing schedule. Continued use of Sialanar has been evaluated in children and adolescents for up to 9 months. Continued use should be evaluated on a regular basis e.g. 3-6 monthly for changes in efficacy and/or tolerability with the dose adjusted as required. Sialanar should not be used in patients <3 years or patients >65 years. ***Renal impairment:*** Reduce dose by 30% in mild to moderate renal impairment. **Method of Administration:** For oral use and use with nasogastric and/or PEG tubes. Oral glycopyrronium bromide products are not interchangeable on a microgram-for-microgram basis due to differences in bioavailability. Care should be taken if switching between oral products and dosing adjusted accordingly. Dose at least one hour before or at least two hours after meals or at consistent times with respect to food intake. Avoid high fat food. Post-dose, flush feeding tubes with 10 ml water. **Contraindications:** Hypersensitivity to the active substance and/or excipients; pregnancy and breast-feeding; glaucoma; urinary retention; severe renal impairment and/or end-stage renal disease requiring dialysis; history of intestinal obstruction, ulcerative colitis, paralytic ileus, pyloric stenosis, myasthenia gravis; concomitant treatment with potassium chloride solid oral dose and/or anticholinergic drugs. **Undesirable effects:** Adverse reactions (ADRs) reported in the literature for glycopyrronium use in paediatric patients with sialorrhoea include: *Common ADRs:* upper respiratory tract infection, pneumonia, urinary tract infection, agitation, drowsiness, nasal congestion, epistaxis, rash, urinary retention and pyrexia. *Very common ADRs:* irritability, flushing, reduced bronchial secretions, dry mouth, constipation, diarrhoea and vomiting. *Serious ADRs:* urinary retention, pneumonia, allergic reaction. The safety profile presented in the Sialanar SmPC is based on ADRs reported in the literature from trials using glycopyrronium for sialorrhoea in the paediatric population, including the SALIVA trial - a 12-week randomised, double-blind, placebo-controlled trial followed by a 24-week open-label study extension (OLSE) in paediatric patients treated with Sialanar. The SmPC should be consulted for the full list of adverse reactions. **Special warnings and precautions:** Carer should stop treatment and seek advice from the prescriber in the event of constipation, urinary retention, pneumonia, allergic reaction, pyrexia, very hot weather and/or changes in behaviour. Not for mild to moderate sialorrhoea. Use with caution in cardiac, gastro-intestinal, dental and/or respiratory disorders. Risk of increased CNS ADRs, with particular caution in patients with a compromised blood brain barrier. Caution with concomitant use of: antispasmodics, topiramate, skeletal muscle relaxants, sedating antihistamines, neuroleptics/antipsychotics, opioids, tricyclic antidepressants and MAOIs, other medicines with anticholinergic properties and/or corticosteroids. Sialanar contains 2.3 mg sodium benzoate (E211) in each ml. Less than 1 mmol sodium (23 mg) is contained per maximum dose. Moderate influence on ability to drive/use machines. **Legal classification:** POM. **Further information available on request from the Marketing Authorisation Holder.**
Date of last revision: August 2026

For the United Kingdom
Marketing Authorisation Holder: Proveca Pharma Ltd. 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland. **Basic NHS price:** Sialanar 250ml bottle, £320; Sialanar 60ml bottle, £76.80. **Marketing Authorisation Number:** PLGB 42588/0003

Adverse events should be reported. Reporting forms and information can be found at: yellowcard.mhra.gov.uk
Adverse events should also be reported to Proveca Limited.
Phone: +44 333 200 1866 | E-mail: medinfo@proveca.co.uk