Prescribing Information (Republic of Ireland and Europe)

Sialanar (400 mcg/ml glycopyrronium bromide, equivalent to 320 mcg/ml glycopyrronium) 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) in children and adolescents aged 3 years and older with chronic neurological disorders. **Dosage**: Start with approximately 12.8 mcg/kg body weight of glycopyrronium 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 64 mcg/kg body weight glycopyrronium or 6ml three times a day, whichever is less. Monitor at least 3 monthly for changes in efficacy and/or tolerability and adjust dose as needed. Not for patients less than 3 or over 17 years old as Sialanar is indicated for the paediatric population only. ***Renal impairment:*** Reduce dose by 30% in mild/moderate renal impairment. **Method of Administration:** Oral use only. Dose at least one hour before or two hours after meals or at consistent times with respect to food intake. Avoid high fat food. Post-dose, flush nasogastric 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 more common with higher doses and prolonged use. Common adverse reactions reported in the literature for glycopyrronium use in paediatric patients with sialorrhoea include: upper respiratory tract infection, pneumonia, urinary tract infection, agitation, drowsiness, epistaxis, rash and pyrexia. Very common adverse reactions include irritability, flushing, nasal congestion, reduced bronchial secretions, dry mouth, constipation, diarrhoea, vomiting and urinary retention. Serious adverse reactions include urinary retention, pneumonia, allergic reaction. 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. Lack of long-term safety data (>24 weeks) so treatment duration should be kept as short as possible but where continuous or repeated intermittent treatment is required, benefits and risks should be considered on a case-by-case basis. Not for mild to moderate sialorrhoea. Use with caution in cardiac, gastro-intestinal, dental and/or respiratory disorders. Risk of increased CNS adverse reactions, with particular caution in patients with a compromised blood brain barrier. Caution with concomitant use of: antispasmodics, topiramate, sedating antihistamines, neuroleptics/antipsychotics, skeletal muscle relaxants, tricyclic antidepressants and MAOIs, opioids, other medicines with anticholinergic properties and/or corticosteroids. Sialanar contains 2.3 mg sodium benzoate (E211) in each ml. 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: June 2026.

For the Republic of Ireland
Marketing Authorisation Holder: Proveca Pharma Ltd. 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland. **Pack Sizes:** Sialanar 250ml bottle. Sialanar 60ml bottle (hospital use only). **Marketing Authorisation Numbers**: Sialanar 250ml bottle - EU/1/16/1135/001; Sialanar 60ml Bottle - EU/1/16/1135/002.

Sialanar is a prescription only medicine licensed throughout the EU, EEA and UK.
Sialanar is not currently marketed in all territories. Not all strengths or pack sizes are available in all territories.

Adverse events should be reported.
For Republic of Ireland: Reporting forms and information can be found at: www.hpra.ie
For the EU: Please follow the local adverse event reporting process.
Adverse events should also be reported to Proveca Limited.
Phone: +44 333 200 1866 E-mail: medinfo@proveca.com