Prescribing Information – Republic of Ireland
Sialanar®(320mcg/ml glycopyrronium)

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

Presentation: Glycopyrronium oral solution in 250 ml bottle. 1 ml solution contains 320 micrograms glycopyrronium (equivalent to 400 micrograms/ml or 2mg/5ml glycopyrronium bromide).

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 micrograms/kg body weight of glycopyrronium per dose, three times per day. Increase dose weekly until efficacy is balanced with side effects. Titrate to maximum individual dose of 64 mcg/kg body weight glycopyrronium or 6 ml three times a day, whichever is less. Monitor at least 3 monthly for changes in efficacy and/or tolerability and adjust dose if needed. Not for patients less than 3 or over 17 years old as Sialanar is indicated for the paediatric population only. Reduce dose by 30%, in mild/moderate renal failure. Dose at least one hour before or two hours after meals or at consistent times with respect to food intake. Avoid high fat food. Flush nasogastric tubes with 10 ml water.

Contraindications: Hypersensitivity to active substance or excipients; pregnancy and breast-feeding; glaucoma; urinary retention; severe renal impairment/dialysis; history of intestinal obstruction, ulcerative colitis, paralytic ileus, pyloric stenosis; myasthenia gravis; concomitant treatment with potassium chloride solid oral dose or anticholinergic drugs.

Special warnings and precautions for use: Monitor anticholinergic effects. Carer should stop treatment and seek advice in the event of constipation, urinary retention, pneumonia, allergic reaction, pyrexia, very hot weather or changes in behaviour. For continuous or repeated intermittent treatment, consider benefits and risks on case-by-case basis. Not for mild to moderate sialorrhoea. Use with caution in cardiac disorders; gastro-oesophageal reflux disease; pre-existing constipation or diarrhoea; compromised blood brain barrier; in combination with: antispasmodics, topiramate, sedating antihistamines, neuroleptics/antipsychotics, skeletal muscle relaxants, tricyclic antidepressants and MAOIs, opioids or corticosteroids. Sialanar contains 2.3 mg sodium benzoate (E211) in each ml. Patients require daily dental hygiene and regular dental checks. Thicker secretions may increase risk of respiratory infection and pneumonia. Moderate influence on ability to drive/use machines.

Fertility, pregnancy and lactation: Use effective contraception. Contraindicated in pregnancy and breast feeding.

Undesirable effects: Adverse reactions more common with higher doses and prolonged use. In placebo-controlled studies (≥15%) dry mouth, constipation, diarrhoea and vomiting, urinary retention, flushing and nasal congestion. In paediatric literature; *very common:* irritability, reduced bronchial secretions; *common*: upper respiratory tract infection, pneumonia, urinary tract infection, agitation, drowsiness, epistaxis, rash, pyrexia. The Summary of Product Characteristics should be consulted for a full list of side effects.

Shelf life: 3 years unopened. 2 months after first opening.

MA number: Sialanar 250 ml bottle - EU/1/16/1135/001;
Sialanar 60ml Bottle (hospital use only)- EU/1/16/1135/002

Legal Category: POM

Marketing Authorisation Holder (MAH): Proveca Pharma Ltd. 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland

Further prescribing information can be obtained from the MAH.

Date of last revision of prescribing information: September 2022

Adverse events should be reported. Reporting forms and information can be found at: www.hpra.ie
Adverse events should also be reported to Proveca Limited.
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