# Sialanar®

**400mcg/ml glycopyrronium bromide equivalent to 320mcg/ml glycopyrronium**

## Sialanar® dose conversion from 1mg/5ml glycopyrronium bromide oral solutions

Sialanar® is licensed for the symptomatic treatment of severe sialorrhoea in children and adolescents aged 3 years and older, with chronic neurological disorders.[1]

**The table opposite provides guidance on the equivalent doses of 1mg/5ml glycopyrronium bromide oral solutions[2,3] and Sialanar® (2mg/5ml glycopyrronium bromide) oral solution[1], due to differences in concentration and bioavailability.**

**Doses are provided as per the respective product SmPCs and are for patients with normal renal function.**

### BNFC Guidance[4]

- Oral preparations are not interchangeable on a microgram-for-microgram basis due to differences in bioavailability.
- Sialanar® oral solution has approximately 25% higher bioavailability and therefore equivalent doses will be lower than for tablets and generic oral solutions.
- The prescriber should state the specific branded or generic oral preparation to be used; care should be taken if switching between oral preparations and dosing adjusted accordingly.

**This item is intended for HCPs, prescribing information and adverse event reporting can be found on page 2.**

| | | 1mg/5ml glycopyrronium bromide oral solution dose | | Sialanar® 2mg/5ml glycopyrronium bromide oral solution dose | |
|---|---|---|---|---|---|
| Weight of child (kg) | Dose level | mg | ml | mg | ml |
| 13-17 | 1 | 0.30 | 1.5 | 0.24 | 0.6 |
| | 2 | 0.60 | 3.0 | 0.48 | 1.2 |
| | 3 | 0.90 | 4.5 | 0.72 | 1.8 |
| | 4 | 1.20 | 6.0 | 0.96 | 2.4 |
| | 5 | 1.50 | 7.5 | 1.20 | 3.0 |
| 18-22 | 1 | 0.40 | 2.0 | 0.32 | 0.8 |
| | 2 | 0.80 | 4.0 | 0.64 | 1.6 |
| | 3 | 1.20 | 6.0 | 0.96 | 2.4 |
| | 4 | 1.60 | 8.0 | 1.28 | 3.2 |
| | 5 | 2.00 | 10.0 | 1.60 | 4.0 |
| 23-27 | 1 | 0.50 | 2.5 | 0.40 | 1.0 |
| | 2 | 1.00 | 5.0 | 0.80 | 2.0 |
| | 3 | 1.50 | 7.5 | 1.20 | 3.0 |
| | 4 | 2.00 | 10.0 | 1.60 | 4.0 |
| | 5 | 2.50 | 12.5 | 2.00 | 5.0 |
| 28-32 | 1 | 0.60 | 3.0 | 0.48 | 1.2 |
| | 2 | 1.20 | 6.0 | 0.96 | 2.4 |
| | 3 | 1.80 | 9.0 | 1.44 | 3.6 |
| | 4 | 2.40 | 12.0 | 1.92 | 4.8 |
| | 5 | 3.00 | 15.0 | 2.40 | 6.0 |
| 33-37 | 1 | 0.70 | 3.5 | 0.56 | 1.4 |
| | 2 | 1.40 | 7.0 | 1.12 | 2.8 |
| | 3 | 2.10 | 10.5 | 1.68 | 4.2 |
| | 4 | 2.80 | 14.0 | 2.24 | 5.6 |
| | 5 | 3.00 | 15.0 | 2.40 | 6.0 |
| 38-42 | 1 | 0.80 | 4.0 | 0.64 | 1.6 |
| | 2 | 1.60 | 8.0 | 1.28 | 3.2 |
| | 3 | 2.40 | 12.0 | 1.92 | 4.8 |
| | 4 | 3.00 | 15.0 | 2.40 | 6.0 |
| | 5 | 3.00 | 15.0 | 2.40 | 6.0 |
| 43-47 | 1 | 0.90 | 4.5 | 0.72 | 1.8 |
| | 2 | 1.80 | 9.0 | 1.44 | 3.6 |
| | 3 | 2.70 | 13.5 | 2.16 | 5.4 |
| | 4 | 3.00 | 15.0 | 2.40 | 6.0 |
| | 5 | 3.00 | 15.0 | 2.40 | 6.0 |
| ≥48 | 1 | 1.00 | 5.0 | 0.80 | 2.0 |
| | 2 | 2.00 | 10.0 | 1.60 | 4.0 |
| | 3 | 3.00 | 15.0 | 2.40 | 6.0 |
| | 4 | 3.00 | 15.0 | 2.40 | 6.0 |
| | 5 | 3.00 | 15.0 | 2.40 | 6.0 |

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# Prescribing Information

## Sialanar 320 micrograms /ml oral solution
## Please refer to the full Summary of Product Characteristics (SmPC) before prescribing

**Presentation:** Glycopyrronium oral solution in 250 ml or 60 ml bottle. 1 ml solution contains 400 micrograms glycopyrronium bromide, (equivalent to 320 micrograms of the active ingredient, 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 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 for Great Britain (England, Scotland, Wales):** PLGB 42588/0003. **MA number for Northern Ireland:** Sialanar 250 ml bottle - EU/1/16/1135/001; Sialanar 60ml Bottle - EU/1/16/1135/002. **Legal Category:** POM. **Basic NHS Price:** Sialanar 250 ml bottle £320. Sialanar 60ml Bottle £76.80. **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:** January 2023.

**Adverse events should be reported.**
**Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard.**
**Adverse events should also be reported to Proveca Limited.**
**Phone: 0333 200 1866**
**E-mail: medinfo@proveca.com**


**References:**

1. Sialanar® SmPC, Jan 2023. https://www.medicines.org.uk/emc/product/2301 Last accessed: May 2023.
2. Colonis Glycopyrronium Bromide 1mg/5ml SmPC, Sep 2021. https://www.medicines.org.uk/emc/product/7344 Last accessed: May 2023.
3. Rosemont Glycopyrronium Bromide 1mg/5ml SmPC, Jan 2022. https://www.medicines.org.uk/emc/product/13136 Last accessed: May 2023.
4. BNFC Glycopyrronium Bromide https://bnfc.nice.org.uk/drugs/glycopyrronium-bromide/ Last accessed: May 2023.


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