Glycopyrronium Dosing for Hypersalivation in Children & Adolescents

Information for prescribers

Sialanar® (glycopyrronium 320micrograms/ml) is now the preferred glycopyrronium product in Nottinghamshire (APC Sept18). It is the only glycopyrronium product licensed for hypersalivation in children and adolescents. New patients should be started on Sialanar® and treatment must be recommended by a paediatric specialist.

Dosing for patients newly started on Sialanar® (taken from SPC accessed 21/9/18)
Sialanar® is licensed for symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.

Note that the BNF for Children doses are listed as the salt, glycopyrronium bromide, and the SPC for Sialanar® lists doses as the base, glycopyrronium. The advice in the BNF is to refer to the product literature for Sialanar® dosing® (see below).

Sialanar® SPC dosing: 12.8 micrograms/kg per dose (equivalent to 16 micrograms/kg per dose glycopyrronium bromide), three times per day and increasing by the doses shown in Table 1 below, every 7 days as appropriate. Max. individual dose of 64 micrograms/kg body weight glycopyrronium or 6 ml (1.9 mg glycopyrronium, equivalent to 2.4 mg glycopyrronium bromide) three times a day, whichever is less.

Table 1: Dosing table for children and adolescents with normal renal function

Weight	Dose Level 1	Dose Level 2	Dose Level 3	Dose Level 4	Dose Level 5
Kg	(~12.8µg/kg) [1]	(~25.6µg/kg) [1]	(~38.4µg/kg) [1]	(~51.2µg/kg) [1]	(~64µg/kg) [1]
	ml	ml	ml	ml	ml
13-17	0.6	1.2	1.8	2.4	3
18-22	0.8	1.6	2.4	3.2	4
23-27	1	2	3	4	5
28-32	1.2	2.4	3.6	4.8	6*
33-37	1.4	2.8	4.2	5.6	6
38-42	1.6	3.2	4.8	6*	6
43-47	1.8	3.6	5.4	6	6
≥48	2	4	6*	6	6

[1] refers to µg/kg glycopyrronium

*Maximum individual dose in this weight range

Hepatic impairment

Clinical studies have not been conducted in patients with hepatic impairment. Glycopyrronium is cleared predominantly from the systemic circulation by renal excretion and hepatic impairment is not thought to result in a clinically relevant increase in systemic exposure of glycopyrronium.

Renal impairment

- Mild to moderate renal impairment (eGFR <90 - ≥30 ml/min/1.73m2) doses should be reduced by 30% (See SPC for dosing table for renal impairment)
- Contraindicated in severe renal impairment (eGFR <30 ml/min/1.73m2), including those with end-stage renal disease requiring dialysis.

Administration instructions

The dose should be given 1 hour before meals or 2 hours after meals.
It is important that the dose is given at consistent times in relation to food intake. Do not give with high fat foods.

Shelf life

Once the bottle is opened, Sialanar® can be used for TWO months. Please ask the carer to write the date the bottle was opened on the label to help keep track. All of the liquid in the bottle should be used before opening the next unless it has been open for more than two months.