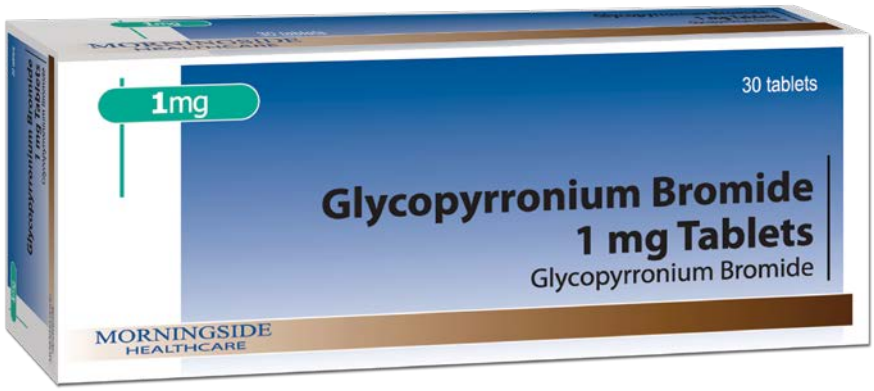
Glycopyrronium Bromide for Paediatric Use



Glycopyrronium Bromide is often used in children with neurodisability to control upper airway secretions.

Since 2017, there is a licenced paediatric preparation available in Ireland called Sialanar 320 micrograms/ml oral solution, which is GMS reimbursable. Prior to the availability of Sialanar, oral solutions were only available as exempt/ unlicenced medicinal products which were also GMS reimbursable.

The IPU Product File has been approached by pharmacists in LauraLynn Children's Hospice in relation to medication errors they have noticed at patient admission. The errors are occurring with glycopyrronium bromide oral solution that is prescribed by general paediatricians or GPs and dispensed by community pharmacists.

Errors occur due to the fact that the 320 micrograms in the name of this product refers to glycopyrronium, when dosing in the BNF for Children and other paediatric references are often stated as glycopyrronium bromide.

Caution is required in interpreting the strength of the licenced product. Sialanar is a centrally authorised product, meaning it has an authorisation granted by the EMA which is valid across the whole of the European Union. The full name of the product as per the SPC is 'Sialanar 320 micrograms/ml oral solution'. This is the name and strength that therefore appears on the outer carton and on the bottle of the oral solution. It is also the name and strength that will appear on the dispensary software systems and that will print out on the dispensary label in the pharmacy.

However, Section 2 of the SPC states that "Each ml contains 400 micrograms of glycopyrronium bromide equivalent to 320 micrograms of glycopyrronium". This statement also appears on the outer carton and on the bottle of the product.

For the control of upper airway secretions, the BNF for Children states:

"Child - Initially 16 micrograms/kg 3 times a day, increased in steps of 16 micrograms/kg 3 times a day, every 7 days, adjusted according to response: maximum 80 micrograms/ kg 3 times a day (max. per dose 2.4 mg). Doses in BNF Publications are expressed as glycopyrronium bromide, however doses may be expressed as glycopyrronium in other literature".

The SPC for Sialanar states "The dosing schedule for glycopyrronium is based on the weight of the child, starting with approximately 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 seven days."

320 micrograms/ml of glycopyrronium is equivalent to 400 micrograms/ml of glycopyrronium bromide.

Glycopyrrolate 1mg = Glycopyrronium Bromide 1mg = Glycopyrronium 0.8mg

Care needs to be taken with paediatric prescriptions for glycopyrronium bromide to ensure correct dose conversions and to check carefully the strength of the product that is being dispensed.

Unlicenced or exempt oral solutions are available and the strengths in the names of these products is usually expressed as glycopyrronium bromide.

Unlicenced products are available in the following strengths: 0.1mg/ml, 0.2mg/ml, 0.5mg/ml and 1mg/ml. However, pharmacists should be aware, and should inform prescribers, that 'exempt' medicinal products should not be sourced and supplied if a suitable authorised alternative is available in Ireland. Sialanar is licenced and is available from the usual wholesalers and should be the preferred choice of product where suitable.

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

Weight Kg	Dose level 1 (~12.8µg/kg) [1] ml	Dose level 2 (~25.6µg/kg) [1] ml	Dose level 3 (~38.4µg/kg) [1] ml	Dose level 4 (~51.2µg/kg) [1] ml	Dose level 5 (~64µg/kg) [1] 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

Table 1 in Section 4 of the Sialanar SPC shows the dose in ml of solution to be given for each weight range at each dosing increase. Note that the doses are expressed as glycopyrronium.

The HPRA issued an advisory safety notice in September 2019 (interpreting strength in the product name for active substances in their salt form) highlighting the potential for confusion that can occur with different salts forms: *http://www.hpra.ie/homepage/medicines/safety-notices/item?t=/interpreting-strength-in-the-product-name-for-active-substances-in-their-salt-form&id=af6c0c26-9782-6eee-9b55-ff00008c97d0*