Package leaflet: Information for the patient

Glycopyrronium bromide 1mg /5 ml oral solution

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for them.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Glycopyrronium bromide 1 mg/5 ml oral solution is and what it is used for
2. What you need to know before you give Glycopyrronium bromide 1 mg/5 ml oral solution
3. How to use Glycopyrronium bromide 1 mg/5 ml oral solution
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1. What Glycopyrronium bromide 1 mg/5 ml oral solution is and what it is used for

This medicine is called Glycopyrronium bromide 1 mg/5 ml oral solution and belongs to a group of medicines called anticholinergic or antimuscarinic drugs. It contains the active substance glycopyrronium bromide. Each 5 ml dose of oral solution contains 1 mg of glycopyrronium bromide.

Glycopyrronium bromide 1 mg/5 ml oral solution is used to treat excessive production of saliva (sialorrhoea) in children and adolescents aged 3 years and older. Sialorrhoea (drooling or excessive salivation) is a common symptom of many diseases of the muscles or nerves. It is mainly caused by poor control of muscles in the face. Acute sialorrhoea may be associated with inflammation, dental or mouth infections. Glycopyrronium bromide 1 mg/5 ml oral solution acts on the salivary glands to reduce production of saliva.

2. What you need to know before you give Glycopyrronium bromide 1 mg/5 ml oral solution

Do not give Glycopyrronium bromide 1 mg/5 ml oral solution if the child:
- is **allergic** (hypersensitive) to glycopyrronium bromide or any of the other ingredients of this medicine (listed in section 6)
- has **glaucoma** (increased pressure in the eye)
- has a condition called **myasthenia gravis** which leads to muscle weakness and fatigue
- has an **obstruction of the stomach** (pyloric stenosis) **or bowel** causing vomiting, abdominal pain and swelling (paralytic ileus)
- has an enlarged prostate gland (prostatic hypertrophy)
- is unable to completely **empty the bladder** (urinary retention)
- suffers from **chronic end stage kidney disease** and require dialysis
- is taking **potassium chloride** solid dose products
- is taking **anticholinergic medicines**

Warnings and precautions
Talk to a doctor or pharmacist before giving Glycopyrronium bromide 1 mg/5 ml oral solution if the child:
- has **gastric reflux** (a condition in which the liquid stomach contents backs up into the gullet)
- has **ulcerative colitis** (a chronic inflammation of the large intestine (colon) which can cause abdominal pain, diarrhoea and bleeding from the back passage)
- **pre-existing constipation**
- has just had a **heart attack** or are suffering from **heart disease, irregular heartbeats** or **high blood pressure**, because this medicine can cause a change to their normal heart rate
- has a condition characterised by a **faster heartbeat** than normal (this can be caused by conditions such as an **overactive thyroid gland, heart failure** or **heart surgery**)
- is due to have **surgery** (including at the dentist) during which they will be 'put to sleep' using **inhalation anaesthesia**. This is because this medicine may cause a change in their normal heart rhythm
- has **diarrhoea**, especially if they have had an **ileostomy** or **colostomy**
- has a **high temperature** (fever) or the environmental temperature is high (e.g. hot weather outside and high room temperature inside), as this medicine will reduce the amount they sweat, making it harder for their body to cool down. The doctor may need to temporarily reduce the dose given.
- has **kidney disease,** because this medicine's dose may need to be decreased
- has **compromised blood brain barrier** (e.g. brain shunt/tumour and swollen brain can compromise blood brain barrier)
- has been told by their doctor that they have an **intolerance to some sugars,** because this medicine contains sorbitol

In addition, stop treatment and talk to their doctor if the child is suffering with the following:
- seem unwell with a very fast or very slow heart rate
- constipation
- pneumonia
- changes in behaviour

The doctor will decide if treatment should continue and if there should be a dose reduction, after evaluating any of these events. If you are not sure any of the above applies to your child, talk to a doctor or pharmacist before giving Glycopyrronium bromide 1 mg/5 ml oral solution.

Glycopyrronium bromide 1 mg/5 ml oral solution reduces salivation which can increase the risk of dental disease, therefore teeth should be brushed daily and have regular dental checks.

Children under 3 years
This medicine is **not recommended for children younger than 3 years**. Talk to a doctor or pharmacist before taking this medicine or if this medicine has been prescribed for a child less than 3 years.

Other medicines and Glycopyrronium bromide 1 mg/5 ml oral solution
Tell the doctor or pharmacist if your child is taking, have recently taken, or might take any other medicines. This includes medicines you have bought without a prescription.

If their doctor tells you to give both this medicine and one or more **similar medicines** such as **oxybutynin**, then they may need to take less than the usual dose of this medicine. This is because of an **increased risk** of other **side effects** such as dry mouth, retention of urine and constipation when glycopyrronium bromide and **similar medicines** are taken together.

Please **tell the doctor** if your child is taking or has recently taken:
- **Antidepressants** such as amitriptyline, clomipramine, lofepramine or imipramine (known as tricyclic antidepressants) or **monoamine oxidase inhibitors (MAOIs)** such as phenelzine, moclobemide, rasagiline, selegiline or tranylcypromine
- **Phenothiazines** such as chlorpromazine, fluphenazine, prochlorperazine or trifluoperazine, used to treat **mental problems** or **nausea, vomiting** or **vertigo**
- **Antihistamines** such as promethazine, used to treat **allergies**
- **Parasympathomimetics** such as carbachol, neostigmine or physostigmine which affect the transmission of nerve impulses to muscles
- **Skeletal muscle relaxants** (botulinum toxin)
- **Opioids** used to treat severe pain
- **Corticosteroids** such as prednisolone, used to treat various conditions including **asthma** and
- **inflammation**
- **Inhaled anaesthetics**, given before surgery (including at the dentist)
- **Clozapine** or **haloperidol**, used to treat **schizophrenia**
- **Nefopam**, used to treat **acute and chronic pain**
- **Domperidone** or **metoclopramide**, used to treat **nausea** and **vomiting**
- **Amantadine** or **levodopa**, used to treat **Parkinson's disease**
- **Memantine**, used to treat **Alzheimer's disease**
- Slow-dissolving **digoxin** tablets, **disopyramide** or **atenolol**, used to treat **heart problems**
- **Metformin**, used to treat **type 2 diabetes**
- **Glyceryl trinitrate** tablets, used to treat **angina**. These may not dissolve under the tongue as well as usual because this medicine can cause a dry mouth
- **Topiramate** or **zonisamide,** used to treat **epilepsy** and to prevent **migraines**
- **Potassium chloride** containing solid dose products (see section 2 "Do not give Glycopyrronium bromide 1 mg/5 ml oral solution if")
- **Anticholinergic medicines**. (see section 2, "Do not give Glycopyrronium bromide 1 mg/5 ml oral solution if")

Long term use efficacy and safety of Glycopyrronium bromide 1 mg/5 ml oral solution has not been studied beyond the recommended 24 weeks of use. Continued use should be discussed with the child's doctor every 3 months to check that Glycopyrronium bromide 1 mg/5 ml oral solution is still right for the child.

Glycopyrronium bromide 1 mg/5 ml oral solution with food and drink
The effect of Glycopyrronium bromide 1 mg/5 ml oral solution may be reduced when taken with high fat foods. For this reason, this medicine should be given at least one hour before or two hours after meals. Speak to the child's doctor if administration with a meal is required.

Pregnancy and breastfeeding
Glycopyrronium bromide 1 mg/5 ml oral solution is not recommended in pregnancy or breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
Glycopyrronium bromide 1 mg/5 ml oral solution may make the patient **feel drowsy** or cause their **eyesight** to become **blurred** and this could interfere with their ability to drive or operate machinery safely. Do not drive or operate machinery until these effects have fully cleared. If there is any doubt, ask your doctor for advice.

Glycopyrronium bromide 1 mg/5 ml oral solution contains sorbitol (E420), sodium benzoate (E211) and sodium.
- This medicine contains 175 mg of **sorbitol (E420)** in each 1 ml. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- This medicine contains 0.8 mg **benzoate salt** in each 1 ml.
- This medicinal product contains less than 1 mmol **sodium** (23 mg) per 1 ml, that is to say essentially 'sodium free'.

3. How to use Glycopyrronium bromide 1 mg/5 ml oral solution

Always give this medicine exactly as the doctor has told you. Check with your doctor or pharmacist if you are not sure.

There are other oral solutions with glycopyrronium, but each one can have a different method of administration. Read carefully how to use this medicinal product and check with your doctor or pharmacist if you are not sure. Use only the oral syringe included in the container of Glycopyrronium bromide 1 mg/5 ml oral solution with this product.
This medicine is for oral use only.

This medicine should be given at least **one hour before or two hours after** a meal. Do not give with high fat foods.

Use in children and adolescents aged 3 years and older

The initial dose will be calculated based on the weight of the child. The dose will be decided by the doctor, using the table below as a guide, and will depend on both the effect of Glycopyrronium bromide 1 mg/5 ml oral solution and any side effects the patient is experiencing. Section 4 includes possible side effects related to the use of Glycopyrronium bromide 1 mg/5 ml oral solution. These should be discussed with the child's doctor, including those for dose increases and decreases, and at any other time should you be concerned. The child should be monitored at regular intervals to check that Glycopyrronium bromide 1 mg/5 ml oral solution is still the right treatment for them.

Weight	Dose Level 1	Dose Level 2	Dose Level 3	Dose Level 4	Dose Level 5
(Kg)	(ml)	(ml)	(ml)	(ml)	(ml)
13-17	1.5	3	4.5	6	7.5
18-22	2	4	6	8	10
23-27	2.5	5	7.5	10	12.5
28-32	3	6	9	12	15
33-37	3.5	7	10.5	14	15
38-42	4	8	12	15	15
43-47	4.5	9	13.5	15	15
≥48	5	10	15	15	15

Directions for use

Give the dose prescribed by your doctor to the child three times each day.
- Insert the tip of the oral syringe into the neck of the bottle.
- Gently pull up the plunger to the correct level (see Table above for the correct dose).
- Once the correct dose has been measured, carefully withdraw the oral syringe from the bottle.
- Take care to avoid spilling the solution.
- Place the tip of the oral syringe inside the child's mouth and press the plunger slowly to gently release the medicinal product.

If your child is given the medicine through a feeding tube, flush the tube with 20 ml of water after you have given the medicine.

This medicine is **not recommended for children less than 3 years of age**. Talk to your doctor or pharmacist before giving this medicine to a child if this medicine has been prescribed for a child less than 3 years.

If you give more Glycopyrronium bromide 1 mg/5 ml oral solution than you should

If you give more of this medicine to the child than has been prescribed, they are more likely to experience side effects. Consult the doctor or **get medical advice immediately**. If possible, give any leftover solution, the bottle and this leaflet to the medical staff so they know what you have given.

If you forget to give Glycopyrronium bromide 1 mg/5 ml oral solution
- If you forget to give a dose, give it as soon as possible. Then give the next dose at the correct time, in accordance with the instructions given to you by the doctor. However, if the next dose is due, do not give the dose missed; just give the next dose as normal.
- **Do not give a double dose to make up for the forgotten one.**

If you have any further questions on the use of this medicine, ask the doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following serious side effects occur, **stop giving the medicine** and **seek medical advice immediately**:
- Severe allergic reaction (swelling of the tongue, lips, face or throat) - unknown
- Constipation (difficulty in passing stools) – very common
- Urinary retention (unable to completely empty the bladder) – common
- Pneumonia (severe chest infection) – common
- Allergic reaction (hives, difficulty breathing or swallowing, itching) – uncommon
- Fever (pyrexia) – common
- Changes in behaviour such as mood changes, irritability – very common

Other side effects:

Very common side effects (may affect more than 1 in 10 people)
- Dry mouth
- Diarrhoea
- Being sick (vomiting)
- Flushing
- Nasal congestion
- Reduced secretions in the chest
- Reduced secretions in the airways

Common side effects (may affect up to 1 in 10 people)
- Upper respiratory tract infection (chest infection)
- Urinary tract infection
- Drowsiness (sleepiness)
- Agitation
- Rash

Uncommon side effects (may affect up to 1 in 100 people)
- Allergy
- Headache
- Involuntary eye movement (nystagmus)
- Bad breath (halitosis)
- Rash (hives)
- Nose bleeds (epistaxis)
- Fungal infection (thrush) of the throat (oesophageal candidiasis)
- Widening of the pupil of the eye (mydriasis)
- Dehydration
- Thirst
- Urgent need to urinate
- Insomnia (difficulty in sleeping)
- Abnormal contractions of digestive tract when food is ingested (gastrointestinal motility disorder)
- A disorder of the muscles and nerves in the intestine which causes an obstruction or blockage (pseudo-obstruction)
- Dizziness

Unknown side effects (frequency cannot be estimated from the available data)
- Nausea
- Angle-closure glaucoma (increased pressure in the eye)
- Photophobia
- Dry eyes
- Angioedema
- Decrease in heart rate (transient bradycardia)
- Sinus infection (sinusitis)
- Skin dryness
- Sweat inhibition

Reporting of side effects

If you notice any side effects, talk to your doctor, pharmacist or nurse. **This includes any possible side effects not listed in this leaflet**. You can also report side effects directly via the Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glycopyrronium bromide 1 mg/5 ml oral solution

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

This medicine should be stored below 25°C in its original packaging to protect from light.
Do not freeze.
After opening, store below 25°C. Discard after 2 months of opening.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Glycopyrronium bromide 1 mg/5 ml oral solution contains

The active substance is glycopyrronium bromide. Each 1 ml of oral solution contains 0.20 mg glycopyrronium bromide.

The other ingredients are:
Glycerol (E422)
Sorbitol (E420) (see section 2)
Sodium citrate
Sodium benzoate (see section 2
Citric acid
Cherry flavour
Sodium saccharin
Sodium hydroxide/Citric acid (for pH-adjustment)
Purified water

What Glycopyrronium bromide 1 mg/5 ml oral solution looks like and contents of the pack

Glycopyrronium bromide 1 mg/5 ml oral solution is a clear, colourless, cherry flavoured liquid supplied in a 150 ml amber glass bottle with a child resistant cap. Each pack contains a carton with one 150 ml bottle and a 10 ml syringe with 0.5 ml graduations.

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This leaflet was last revised in December 2025

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