

Package Leaflet: Information for the Patient

Glycopyrronium Bromide 1 mg/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 you get 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 oral solution is and what it is used for
2. What you need to know before you give Glycopyrronium Bromide oral solution
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1. What Glycopyrronium Bromide oral solution is and what it is used for

This medicine is called Glycopyrronium Bromide 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 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 oral solution acts on the salivary glands to reduce production of saliva.

2. What you need to know before you give Glycopyrronium Bromide oral solution

Do not give Glycopyrronium Bromide 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 **pregnant or breastfeeding**
- is taking **potassium chloride** solid dose products
- is taking **anticholinergic medicines**

Warnings and precautions

Talk to a doctor or pharmacist before giving Glycopyrronium Bromide 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)
- 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, as this medicine will reduce the amount they sweat, making it harder for their body to cool down
- has **kidney disease**, because this medicine’s dose may need to be decreased
- has **compromised 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 oral solution.

Glycopyrronium Bromide oral solution reduces salivation which can increase the risk of dental disease, therefore teeth should be brushed daily and have regular dental checks.

Children

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 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 have 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
- **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 oral solution if")
- **Anticholinergic medicines**. (see section 2, "Do not give Glycopyrronium Bromide oral solution if")

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

Pregnancy and breastfeeding

Glycopyrronium Bromide oral solution must not be given if the patient is pregnant or breastfeeding (see section 2 "Do not give Glycopyrronium Bromide oral solution if"). Discuss the need for contraception with the doctor.

Driving and using machines

Glycopyrronium Bromide 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 oral solution contains E420 (sorbitol), E217 and E219

- This medicine contains **sorbitol (E420)**. If you have been told by the doctor that your child has an **intolerance to some sugars**, contact the doctor before giving this medicinal product.
- This medicine contains **sodium propyl parahydroxybenzoate (E217)** and **sodium methyl parahydroxybenzoate (E219)**. These may cause **allergic reactions** (possibly delayed) and exceptionally, bronchospasms (a narrowing of the airways).
- This medicinal product contains less than 1 mmol sodium (23 mg) per maximum dose, i.e. essentially is 'sodium free'.

3. How to use Glycopyrronium Bromide oral solution

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

This medicine is for oral use only.

This medicine should be given at least **one hour before or two hours after** a meal.

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 oral solution and any side effects the patient is experiencing. Section 4 includes possible side effects related to the use of Glycopyrronium Bromide 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 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.
- Remove the child-resistant closure from the bottle. Insert the syringe adaptor with the hole into the neck of the bottle (this may have been done already by the pharmacist). Insert the end of the oral syringe into the syringe adaptor and ensure it is secure.
- Hold the oral syringe in place and turn the bottle upside down. Gently pull down the plunger to the correct level (see the tables for the correct dose). Check you have the correct level. The maximum volume of the highest dose is 15 ml.
- Turn the bottle upright. Remove the oral syringe by holding the bottle and twisting the oral syringe gently.
- Place the oral syringe inside the child's mouth and press the plunger slowly to gently release the medicine. After use, leave the syringe adaptor in the neck of the bottle.
- Repeat the above steps if a higher dosage (e.g. 10.5 ml or above) is recommended for you.
- Replace the closure.
- The oral syringe should be washed with warm water and allowed to dry after each use (i.e. three times per day).



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 oral solution than you should

If you give more of this medicine than they have 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 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)

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 to the relevant medicines authority (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Glycopyrronium Bromide 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 label after EXP. The expiry date refers to the last day of that month.
- This medicine should be stored below 25°C in its original bottle.
- Do not freeze.
- Keep the bottle in the original carton in order to protect from light.
- **Once the bottle has been opened, this medicine should be used within 28 days.**
- 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 oral solution contains

- The active substance is glycopyrronium bromide. Each 5 ml of oral solution contains 1 mg of glycopyrronium bromide.
- The other ingredients are:
 - Glycerol
 - Sorbitol (E420) (see section 2)
 - Sodium methyl parahydroxybenzoate (E219) (see section 2)
 - Sodium propyl parahydroxybenzoate (E217) (see section 2)
 - Citric acid monohydrate
 - Trisodium citrate dihydrate
 - Strawberry flavour:
 - Flavouring substance
 - Maltodextrin (maize)
 - Acacia (E414)
 - Triacetin (E1518)

What Glycopyrronium Bromide oral solution looks like and contents of the pack

Glycopyrronium Bromide oral solution is a clear, colourless, strawberry flavoured liquid supplied in a 150 ml amber glass bottle with a child resistant cap. Each pack contains one 150 ml bottle, a 10 ml syringe and a syringe adaptor.

Marketing Authorisation Holder

Colonis Pharma Limited

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United Kingdom

Manufacturers

Labialfarma

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