

## Package leaflet: Information for the user

### Glycopyrronium Bromide 1 mg/5 ml oral solution glycopyrronium bromide

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 take Glycopyrronium bromide oral solution
3. How to take Glycopyrronium bromide oral solution
4. Possible side effects
5. How to store Glycopyrronium bromide oral solution
6. Contents of the pack and other information

#### **1. What Glycopyrronium bromide oral solution is and what it is used for**

This medicine contains glycopyrronium bromide which belongs to a group of medicines called ‘anticholinergic’ or ‘antimuscarinic’ drugs.

**This medicine is used to treat** ‘drooling’ or 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 take Glycopyrronium bromide oral solution**

**Do not give Glycopyrronium Bromide oral solution if the child:**

- is **allergic** 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 or bowel** causing vomiting, abdominal pain and swelling
- has an **enlarged prostate gland**
- is unable to completely **empty the bladder**
- suffers from **chronic end-stage kidney disease** and requires dialysis
- is **pregnant** or **breastfeeding**
- is taking a medicine containing **potassium chloride**
- is taking **anticholinergic medicines**

#### **Warnings and precautions**

Talk to a doctor or pharmacist before giving this medicine 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, diarrhea and bleeding from the back passage)
- has just had a **heart attack** or is suffering from **heart disease**, **irregular heartbeats** or **high blood pressure**, because this medicine can cause a change to their normal heart rate
- has 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 a general anaesthetic.
- has **diarrhoea**, especially if they have had an ileostomy or colostomy
- has a **high temperature** (fever) or the environmental temperature is high,
- has **kidney disease**
- has **compromised blood brain barrier**
- has been told by their doctor that they have an **intolerance to some sugars**

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

This medicine reduces salivation which can increase the risk of dental disease, therefore teeth should be brushed daily and the child should have regular dental checks.

### Children

This medicine is not recommended for children younger than 3 years.

### Other medicines and Glycopyrronium Bromide oral solution

Please tell the doctor if your child is taking or has recently taken any of the following medicines:

- **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
- Medicines 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
- **Medicines** 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 medicines (see section 2 “Do not give Glycopyrronium Bromide oral solution if”)
- **Anticholinergic medicines** (see section 2 “Do not give Glycopyrronium Bromide oral solution if”)

if")

If the doctor tells you to give this medicine together with one or more similar medicines such as oxybutynin, then they may need to take less than the usual dose of this medicine.

### **Pregnancy and breastfeeding**

This medicine must not be given if the patient is pregnant or breastfeeding.  
Discuss the need for contraception with the doctor.

### **Driving and using machines**

This medicine may make the patient feel drowsy or cause their eyesight to become blurred.  
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 sodium benzoate (E211) and 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 medicine. Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.
- This medicine contains less than 1 mmol sodium (23 mg) per maximum dose, i.e. essentially 'sodium free'. This medicine contains 2.3 mg benzoate salt (E211) in each 5 ml of oral solution.

## **3. How to take 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.

### **Dose for children and adolescents aged 3 years and older:**

The initial dose will be calculated based on the weight of the child.

The dose may be adjusted depending on how well they respond to treatment, and if any side effects occur.

The child should be checked by your doctor every 3 months to check that this medicine is still the right treatment for them.

### **When to take the medicine**

The medicine should be given to your child three times each day.

It should be given at least one hour before or two hours after a meal.

### **Directions for use**

- Remove the cap from the bottle. Insert the syringe adaptor into the neck of the bottle (this may have been done already by the pharmacist). Insert the end of the syringe into the adaptor and ensure it is secure.



- Hold the syringe in place and turn the bottle upside down. Gently pull down the plunger to the correct level. The maximum volume of the highest dose is 15 ml.



- Turn the bottle upright. Remove the syringe by holding the bottle and twisting the syringe gently.



- Place the 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 is recommended.
- Replace the cap.
- Wash the syringe with warm water and allow to dry after each use.

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

**If you give more Glycopyrronium Bromide oral solution than you should**

Consult the doctor or get medical advice immediately, as your child may experience side effects. If possible, take the bottle and this leaflet with you so that the medical staff know what you have given.

**If you forget to give Glycopyrronium Bromide oral solution**

- Give it as soon as possible, then give the next dose at the normal time.
- However, if the next dose is due, do not give the missed dose; just give the next dose as normal.
- Do not give a double dose to make up for a forgotten dose.

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

**4. Possible side effects**

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

**Serious side effects**

If any of the following serious side effects occur, stop giving the medicine and seek medical advice immediately:

- Allergic reaction such as swelling of the tongue, lips, face or throat, hives, difficulty breathing or swallowing, itching
- Constipation (difficulty in passing stools)
- Urinary retention (unable to completely empty the bladder)
- Pneumonia (severe chest infection)
- Fever
- Changes in behaviour such as mood changes, irritability

**Other side effects:**

**Very common (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 (may affect up to 1 in 10 people)**

- Upper respiratory tract infection (chest infection)
- Urinary tract infection
- Drowsiness (sleepiness)
- Agitation
- Rash

**Uncommon (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 (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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme at: [www.mhra.gov.uk/yellowcard](http://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 oral solution**

Keep this medicine out of the sight and reach of children.

Do not use Glycopyrronium bromide oral solution after the expiry date which is stated on the label, carton or bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.  
Use within 35 days of opening the bottle.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to 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 anhydrous (E422), sorbitol (E420), sodium benzoate (E211), sucralose (E955), citric acid (E330), strawberry flavouring (containing propylene glycol E1520) and purified water.

### **What Glycopyrronium bromide oral solution looks like and contents of the pack**

Glycopyrronium bromide oral solution is a clear, colourless, strawberry flavoured liquid. Glycopyrronium bromide oral solution is supplied in an amber glass bottle or polyethylene terephthalate (PET) bottle of 150 ml with child resistant tamper evident polypropylene closure, a 10 ml syringe and a syringe adaptor.

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