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132 mm

PHARMACODE READING
DIRECTION

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
3. How to use 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 is called Glycopyrronium Bromide 1 mg/5 ml Oral Solution and belongs to a group of medicines known as quaternary ammonium anticholinergics, which are agents that block or reduce the transmission between nerve cells. This reduced transmission can de-activate the cells that produce saliva.

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 nerves and muscles. It is mostly caused by poor control of muscles in the face. Acute sialorrhoea may be associated with inflammation, dental infections or infections of the mouth. Glycopyrronium bromide Oral Solution acts on the salivary glands to reduce the 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 or adolescent:

- 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
- has **stomach ache and swelling** (paralytic ileus)
- is unable to completely **empty the bladder** (urinary retention)
- suffers from **severe kidney disease**
- is **pregnant or breastfeeding**
- has **diarrhoea** (frequent, loose watery stools)
- has **ulcerative colitis** (inflammation of the intestine)
- is taking any of the following medicines (see Other medicines and Glycopyrronium Bromide Oral Solution):
 - **potassium** chloride solid dose products
 - **anticholinergic** medicines.

Warnings and precautions

Talk to your doctor or pharmacist before giving Glycopyrronium Bromide Oral Solution if the child or adolescent:

- is suffering from **heart disease, irregular heartbeats or high blood pressure**
- has a **high temperature** (fever)
- has **kidney problems** or difficulty in **passing urine**
- has an **abnormal blood brain barrier** (the layer of cells surrounding the brain)
- has digestive disorders (constipation; chronic heartburn and indigestion)
- has an inability to **sweat normally**.

If you are not sure any of the above applies to the child or adolescent, talk to a doctor or pharmacist before giving Glycopyrronium Bromide Oral Solution.

Avoid exposing the child to hot or very warm temperature (hot weather, high room temperature) to avoid over heating and the possibility of heat stroke. Check with the child's doctor during hot weather to see if the dose of Glycopyrronium Bromide Oral Solution should be reduced.

Reduced salivation can increase the risk of dental disease therefore the child's teeth should be brushed daily and they should have regular dental health checks.

Children with kidney problems may be given a lower dose.

Check the child's pulse if they seem unwell. Report a very slow or very fast heart rate to their doctor.

Children under 3 years

This medicine is formulated as an oral formulation and a dose specifically for use in children and adolescents aged 3 years and older.

Glycopyrronium Bromide Oral Solution is not recommended for children under 3 years of age.

Other medicines and Glycopyrronium Bromide Oral Solution

Tell your doctor or pharmacist if your child is taking, has recently taken, or might take any other medicines. This includes medicines you have bought without a prescription. In particular taking Glycopyrronium Bromide Oral Solution with the following medicines can affect the way Glycopyrronium Bromide Oral Solution or the listed medicine works or can increase the risk of side effects:

- potassium chloride solid oral dose (see section above "Do not give Glycopyrronium Bromide Oral Solution if the child or adolescent:")
- anticholinergic medicines (see section above "Do not give Glycopyrronium Bromide Oral Solution if the child or adolescent:")
- antispasmodics used to treat sickness or vomiting e.g. domperidone and metaclopramide
- topiramate used to treat epilepsy
- antihistamines, used to treat some allergies
- neuroleptics/antipsychotics (clozapine, haloperidol, phenothiazine), used to treat some mental illnesses

- skeletal muscle relaxants (botulinum toxin)
- antidepressants (tricyclic antidepressants)
- opioids used to treat severe pain
- corticosteroids, used to treat inflammatory diseases.

Talk to your doctor or pharmacist for further information about medicines to avoid whilst taking Glycopyrronium Bromide Oral Solution.

Long-term use

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

Pregnancy, breast-feeding and fertility

This medicine is intended for use in children and adolescents. Glycopyrronium Bromide Oral Solution must not be given if the patient is pregnant (or could be pregnant), or is breast-feeding (see section 2 'Do not give'). Discuss with the child's doctor whether there is a need for contraception.

Driving and using machines

Glycopyrronium Bromide Oral Solution may affect vision and co-ordination. This may affect performance at skilled tasks such as driving, riding a bicycle, or using machines. After receiving Glycopyrronium Bromide Oral Solution, the patient should not drive a vehicle, ride a bicycle or use a machine until the effect in their vision and co-ordination has completely recovered. Ask your doctor if you need further advice.

Glycopyrronium Bromide Oral Solution contains sorbitol, benzoic acid, propylene glycol and sodium

- This medicine contains 175 mg sorbitol (E420) in each ml. 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. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 1 mg benzoic acid (E210) in each ml.
- This medicine contains 21 mg propylene glycol (E1520) in each ml.
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- If you are pregnant, breast-feeding, suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Glycopyrronium Bromide Oral Solution

Always give this medicine exactly as your 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, or at consistent times in relation to food intake. 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 Oral Solution and any side effects the child may have. Section 4 includes possible side effects related to the use of Glycopyrronium Bromide Oral Solution (this is why several dose levels appear in the table below). These should be discussed with the child's doctor, including the need for dose increases as the child grows, and at any other time should you be concerned. The child should be monitored at regular intervals (at least every 3 months) to check that Glycopyrronium Bromide Oral Solution remain appropriate treatment for them.

Weight kg	Dose Level 1 (~0.02 mg/kg)	Dose Level 2 (~0.04 mg/kg)	Dose Level 3 (~0.06 mg/kg)	Dose Level 4 (~0.08 mg/kg)	Dose Level 5 (~0.1 mg/kg)
13-17	1.5ml	3ml	4.5ml	6ml	7.5ml
18-22	2ml	4ml	6ml	8ml	10ml
23-27	2.5ml	5ml	7.5ml	10ml	12.5ml
28-32	3ml	6ml	9ml	12ml	15ml
33-37	3.5ml	7ml	10.5ml	14ml	15ml
38-42	4ml	8ml	12ml	15ml	15ml
43-47	4.5ml	9ml	13.5ml	15ml	15ml
≥48	5ml	10ml	15ml	15ml	15ml

The maximum recommended dose is 0.1 mg/kg **three times daily** not to exceed 1.5-3 mg (7.5 ml – 15 ml) per dose based upon weight (for further detail see Table above).

Directions for use

- Remove the child-resistant closure from the bottle. Insert the oral 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. Each graduation step of the oral syringe corresponds to 0.5 ml.



- 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.



Size: 280(L) x 420(W) mm
Front Side

420 mm

148 mm

132 mm

- 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.
- 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). Do not use a dishwasher.

If you give more Glycopyrronium Bromide Oral Solution than you should

If you give more of this medicine than the child has been prescribed, side effects are more likely. Consult the doctor or a pharmacist immediately or go to the emergency department of the nearest hospital. Always take any leftover medicine with you, as well as the container and label, so that the medical staff knows 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 you have missed; just give the next dose as normal.

Do not give a double dose to make up for the forgotten one.

If you stop giving Glycopyrronium Bromide Oral Solution

If this is necessary it is best to reduce the dose gradually. Contact your doctor, pharmacist or nurse immediately for advice if they have not given directions to do this. 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.

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

- Allergic reaction (rash, itching, red raised itchy rash (hives), difficulty breathing or swallowing, dizziness) – frequency not known
- Constipation (difficulty in passing stools) – very common
- Difficulty in passing urine (urinary retention) – very common
- Pneumonia (severe chest infection) – common.

The following side effects may be a sign of **severe allergic reaction**. If they occur, take the child to the nearest emergency medical facility and take the medicine with you.

- Swelling mainly of the tongue, lips, face or throat (possible signs of angioedema) – frequency not known.

Other side effects are:

Very common side effects: may affect more than 1 in 10 people

- Dry mouth
- Difficulty in passing stools (constipation)
- Diarrhoea
- Being sick (vomiting)
- Flushing
- Nasal congestion
- Unable to completely empty the bladder (urinary retention)
- Reduced secretions in the chest
- Irritability.

Common side effects: may affect up to 1 in 10 people

- Upper respiratory tract infection (chest infection)
- Pneumonia (severe chest infection)
- Urinary tract infection
- Drowsiness (sleepiness)
- Agitation
- Fever (pyrexia)
- Nose bleeds (epistaxis)
- Rash.

Uncommon side effects: may affect up to 1 in 100 people

- Bad breath (halitosis)
- Fungal infection (thrush) of the throat (oesophageal candidiasis)
- Abnormal contractions of the 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)
- Widening of the pupil of the eye (mydriasis)
- Involuntary eye movement (nystagmus)
- Headache
- Dehydration
- Thirst in hot weather.

Not Known: Side effects where frequency cannot be estimated from the available data

- Allergic reaction (rash, itching, red raised itchy rash (hives), difficulty breathing or swallowing, dizziness)
- Severe allergic reaction (angioedema); signs include swelling mainly of the tongue, lips, face or throat
- Restlessness; overactivity; short attention span; frustration; mood changes; temper outbursts or explosive behaviour; excessive sensitivity; seriousness or sadness; frequent crying episodes; fearfulness
- Insomnia (difficulty in sleeping)
- Raised pressure in the eye (which might cause glaucoma); photophobia (sensitivity to light); dry eyes
- Slow heart rate followed by rapid heart rate, palpitations and irregular heartbeat
- Inflammation and swelling of sinuses (sinusitis)
- Feeling sick (nausea)
- Dry skin
- Reduced ability to sweat, which can cause fever and heatstroke
- Urgent need to urinate.

Side effects can sometimes be difficult to recognise in patients with neurologic problems who cannot easily tell you how they feel.

If you think a troublesome side effect is occurring after increasing a dose, the dose should be decreased to the previous one used and your doctor contacted.

Tell your doctor if you notice any behavioural changes or any other changes in the child.

Reporting of side effects

If you notice 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 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 this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Use within 30 days of opening the bottle.

Store below 25°C. Store in the original package in order to protect from light.

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 contain

The active substance is glycopyrronium bromide.

Each 5 ml dose of oral solution contains 1 mg of glycopyrronium bromide.

The other ingredients are glycerol; sorbitol, liquid (Non-crystallising) (E420); benzoic acid (E210); propylene glycol (E1520); saccharin sodium; sodium citrate; citric acid monohydrate and purified water.

What Glycopyrronium Bromide Oral Solution look like and contents of the pack

Glycopyrronium Bromide 1 mg/5 ml Oral Solution is a clear colourless solution and is available in amber coloured bottles of 150 ml solution packed in an outer carton along with 10 ml oral Syringe (0.5ml graduation) with Adapter.

Marketing Authorisation Holder

Morningside Healthcare Ltd.
Unit C, Harcourt Way
Leicester, LE19 1WP
UK

Manufacturer

Morningside Pharmaceuticals Ltd.
5 Pavilion Way
Loughborough, LE11 5GW
UK

Morningside Pharmaceuticals Ltd. & Aspire Pharma Ltd.
Second Floor, Boss Court, 7 Barton Close, Grove Park
Leicester, LE19 1SJ, United Kingdom

Aspire Pharma Ltd.
Unit 4, Rotherbrook Court
Bedford Road, Petersfield
GU32 3QG, United Kingdom

For information in large print, tape, CD or Braille, please contact medical enquiries on 0116 478 0322.

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Type:	Leaflet
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Black

For submission only