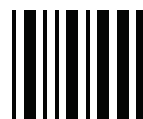
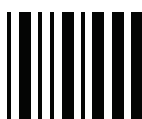


Glycopyrronium Bromide 1mg/5ml Oral Solution glycopyrronium bromide

Read all of this leaflet carefully before your child starts 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 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 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 is and what it is used for
2. What you need to know before you give Glycopyrronium Bromide to a child
3. How to take Glycopyrronium Bromide
4. Possible side effects
5. How to store Glycopyrronium Bromide
6. Contents of the pack and other information

1. What Glycopyrronium Bromide is and what it is used for

What is Glycopyrronium Bromide?

The name of your medicine is Glycopyrronium Bromide.

- It belongs to a group of medicines called 'anti-cholinergics' or 'anti-muscarinics'.

What Glycopyrronium Bromide is used for

It is used when too much saliva is produced (drooling or 'sialorrhoea') in children and young people aged 3 years to less than 18 years

- Too much saliva is common in many diseases of the nerves and muscles. It is mostly caused by poor control of muscles in the face.
- It can also be associated with inflammation, dental infections or infections of the mouth.

How Glycopyrronium Bromide works

The medicine works on the salivary glands to reduce production of saliva.

- The medicine blocks or reduces the messages sent between some nerve cells.
- This can stop saliva cells from producing saliva.

2. What you need to know before you give Glycopyrronium Bromide to a child

Do not give Glycopyrronium Bromide if the child:

- is allergic to Glycopyrronium Bromide or any of the other ingredients of this medicine (listed in Section 6)
- is pregnant or breast feeding
- 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 ulcerative colitis (inflammation of the intestine)
- is unable to completely empty the bladder ('urinary retention')
- has severe kidney disease
- is taking any of the following medicines (see section 'Other medicines and glycopyrronium bromide'):
 - potassium chloride solid oral dosage forms (including tablets and capsules)
 - anti-cholinergic medicines.

Do not give Glycopyrronium bromide if any of the above apply to your child. If you are not sure, talk to your doctor before giving this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before giving Glycopyrronium Bromide if your child has:

- diarrhoea, constipation or gastric reflux (where liquid from the stomach comes back up into the food pipe)
- heart disease, heart failure, irregular heartbeats or high blood pressure. This is because this medicine can change their normal heart rate
- a heart-beat faster than normal (can be caused by an over-active thyroid gland, heart failure or heart surgery)
- a high temperature (fever). This is because this medicine will reduce the amount they sweat, making it harder for their body to cool down
- kidney disease or difficulty passing urine. Children with kidney problems may be given a lower dose
- an abnormal blood brain barrier (the layer of cells surrounding the brain).

If any of the above apply to your child (or you are not sure), talk to your doctor or pharmacist before giving Glycopyrronium Bromide.

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

Dental health

Reduced saliva can increase the risk of dental disease. This means that the child's teeth should be brushed daily. They should also have regular dental health checks.

Illness and pulse rate

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 not recommended for children younger than three years. Talk to your doctor or pharmacist if this medicine has been prescribed for a child younger than three years.

Other medicines and Glycopyrronium Bromide

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

In particular, the following medicines can affect the way this medicine or another medicine works or can increase the risk of side effects. If your child is taking any of the below medicines, talk to their doctor or pharmacist before giving Glycopyrronium Bromide:

- potassium chloride solid oral dosage forms (see section above "Do not give Glycopyrronium Bromide")
- anticholinergic medicines (see section above "Do not give Glycopyrronium Bromide")
- anti-spasmodics – used to treat sickness or vomiting – such as domperidone and metoclopramide
- topiramate – used to treat epilepsy
- anti-histamines – used to treat some allergies
- neuroleptics/antipsychotics (such as clozapine, haloperidol, phenothiazine), used to treat some mental illnesses
- botulinum toxin – used as a muscle relaxant
- anti-depressants called 'tricyclic anti-depressants' such as amitriptyline or 'MAOI anti-depressants'
- medicines for severe pain called 'opioids' such as codeine or pethidine
- corticosteroids – used to treat inflammatory diseases

If your child is taking any of the above medicines, talk to their doctor or pharmacist before giving Glycopyrronium Bromide.

Long-term use

It is not known how effective and safe Glycopyrronium Bromide is beyond 24 weeks of use. If the medicine is used longer than 24 weeks, discuss this with your child's doctor every three months. This is to check that Glycopyrronium Bromide is still right for your child.

Pregnancy and breast-feeding

Glycopyrronium Bromide 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, cycling and using machines

Glycopyrronium Bromide may make the patient feel drowsy or have blurred eyesight. This could affect the ability to drive, cycle or use tools or machines safely. The patient should not drive, cycle or use machines until these effects have fully cleared. If you are not sure, ask your doctor for advice.

Glycopyrronium Bromide Oral Solution contains:

- **sorbitol** (2.45 g per 5 ml dose) - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **sodium benzoate** (3.55 mg per 5 ml dose) - this may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old)
- this medicine contains less than 1 mmol sodium (23 mg) per maximum dose, i.e. essentially 'sodium free'.

3. How to take Glycopyrronium Bromide

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

Children and adolescents 3 years to less than 18 years:

- The doctor will decide the correct dose. The starting dose will be based on the weight of the child.
- The doctor will decide the timing of dose increases – using the table below as a guide.
- The dose will depend on both the effect of Glycopyrronium Bromide and any side effects the patient may have. This is why several dose levels appear in the table.

Section 4 includes possible side effects of glycopyrronium bromide.

- Talk to the child's doctor every time you see them - including for dose increases and decreases. Also talk to them at any other time if you are concerned.
- The child should be monitored at regular intervals to check that Glycopyrronium Bromide is still the right treatment for them.

Weight kg	Dose Level 1 ml	Dose Level 2 ml	Dose Level 3 ml	Dose Level 4 ml	Dose Level 5 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

How much to give

- Give the dose prescribed by your doctor to the child three times each day.
- Give the dose one hour before meals or two hours after meals.
- It is important that the dose is given at consistent times in relation to food intake. Do not give with high fat foods.

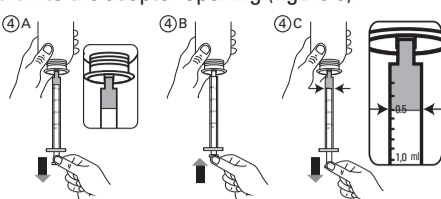
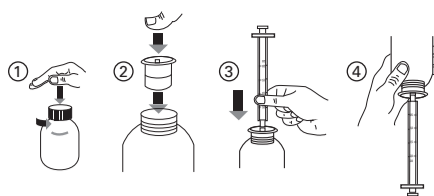
Route of administration

This medicine should be taken by mouth.

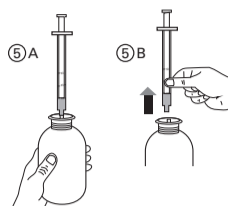
How to use the oral syringe

Use the oral syringe supplied in the pack as instructed:

1. To open the bottle, press the cap down and turn it anti-clockwise (figure 1).
2. Put the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it into the adaptor opening (figure 3).
4. Turn the bottle upside down (figure 4).



5. Fill the syringe with a small amount of solution by pulling the plunger down (figure 4A). Then push the plunger upward to remove any possible bubbles (figure 4B). Finally, pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the piston should be in line with the graduation mark you are measuring to (Figure 4C).
6. Turn the bottle the right way up (Figure 5A).
7. Remove the syringe from the adaptor (Figure 5B).
8. Put the end of the syringe into the child's mouth and push the plunger slowly back in to take the medicine.
9. Wash the syringe with water and let it dry before you use it again.
10. Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.



Taking this medicine via NG or PEG tubes

This medicine can also be administered via gastrostomy tubes such as nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. Ask your doctor, pharmacist or nurse for further information. For use with silicone, PVC and polyurethane gastrostomy tubes **only**.

Instructions for use:

1. Ensure the tube is clear before taking the medicine
2. Flush the enteral tube with water, using the minimum flush volume.
3. Administer the medicine into the tube with a suitable measuring device, which will be provided by your doctor, pharmacist or nurse.
4. Flush the enteral tube with water, using the minimum flush volume.

Tube size (French Units)	Recommended Minimum Flush Volume (ml)
4	1.2
6	2
8	5
10	8
12	10
18	10

If you give more Glycopyrronium Bromide to your child than you should

It is important to make sure an accurate dose is given each time, in order to prevent harmful effects of glycopyrronium seen with dosing errors or overdose. Check that you have drawn up the correct level on the syringe before giving this medicine. Seek medical advice immediately if the child is given too much, even if the child seems well. Take the medicine pack with you.

If you forget to give Glycopyrronium Bromide

- If you forget to give a dose, give it as soon as you remember. However, if it is almost time to take the next dose, skip the missed dose and continue as usual.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop giving Glycopyrronium Bromide to your child

Withdrawal effects are not expected when stopping this medicine. The child's doctor may decide to stop treatment with this medicine if side effects cannot be managed by reducing the 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.

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

Stop using the medicine and get urgent medical advice if any of the following serious side effects occur:

- constipation (difficulty in passing stools) – very common
- difficulty in passing urine (urinary retention) – very common
- pneumonia (severe chest infection) – common
- allergic reaction (rash, itching, red raised itchy rash (hives), difficulty breathing or swallowing, dizziness) – frequency not known

Other side effects

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)
- 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.

Other side effects that occur with anticholinergics but their frequency with glycopyrronium is not known

- 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 heart-beat
- 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 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 your child gets 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, 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

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (month, year) which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not use the medicine 1 month after it is first opened.
- Do not throw away any medicines via wastewater or household waste. 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 1mg/5ml Oral Solution contains

- The active substance is Glycopyrronium Bromide. Each 5ml of the solution contains 1mg Glycopyrronium Bromide.
- The other ingredients are citric acid monohydrate, sodium citrate, sodium benzoate, strawberry flavour, liquid sorbitol, glycerol and purified water.

What Glycopyrronium Bromide 1mg/5ml Oral Solution looks like and contents of the pack

Glycopyrronium Bromide 1mg/5ml Oral Solution is a clear colourless to straw yellow solution. It comes in a brown glass bottle holding 150ml or 250ml of solution with a 10 ml purple oral syringe and bottle adaptor.

Marketing Authorisation Holder and Manufacturer

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