

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
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1. WHAT GLYCOPYRRONIUM BROMIDE ORAL SOLUTION IS AND WHAT IT IS USED FOR

Glycopyrronium bromide (the active substance in Glycopyrronium bromide Oral Solution) belongs to a group of medicines called 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 Oral Solution is used to treat excessive production of saliva (sialorrhoea) in patients suffering from long term neurological disorders which have occurred in childhood, in patients 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 TAKE GLYCOPYRRONIUM BROMIDE ORAL SOLUTION

DO NOT take Glycopyrronium bromide Oral Solution and talk to your doctor if you:

- are allergic to glycopyrronium bromide or any of the ingredients of this medicine (listed in section 6 at the end of the leaflet)
- are pregnant or breastfeeding
- suffer from glaucoma (increased pressure in the eye)
- are unable to completely empty the bladder (urinary retention)
- have severe kidney disease
- have an enlarged prostate gland (prostatic hypertrophy)
- have an obstruction of the stomach (pyloric stenosis) or bowel causing vomiting
- have ulcerative colitis (inflammation of the intestine)
- have diarrhoea (frequent, loose watery stools)
- have a stomach ache and swelling (paralytic ileus)
- have myasthenia gravis (muscle weakness and fatigue)
- are over 65 years of age
- are taking any of the following medicines (see section Other medicines and Glycopyrronium bromide Oral Solution):
 - potassium chloride solid oral dose;
 - anticholinergic medicines.

Tell your doctor if you are not sure about any of the above.

Warnings and precautions

Talk to your doctor or pharmacist before taking Glycopyrronium bromide Oral Solution if you (or the patient) have:

- heart disease, irregular heartbeats or high blood pressure, because this medicine can cause a change to your normal heart rate
- digestive disorders (constipation; chronic heartburn and indigestion)
- a high temperature (fever), as this medicine will reduce the amount you may sweat, making it harder for your body to cool down
- inability to sweat normally
- kidney problems or difficulty passing urine, because the dose of this medicine may need to be reduced
- an abnormal blood-brain barrier (the layer of cells surrounding the brain).

Avoid exposure to hot or very warm temperatures (hot weather, high room temperature) to avoid overheating and the possibility of heatstroke. Check with the patient's doctor during hot weather to see if the dose of this medicine should be reduced.

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

Patients with kidney problems may be given a lower dose.

If you (or the patient) feel unwell, check your pulse and report any slow or very fast heart rate to your doctor.

Children

This medicine is NOT recommended for use in children under 3 years of age (see section 3).

Other medicines and Glycopyrronium bromide Oral Solution

Tell your doctor or pharmacist if you or the patient are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 take Glycopyrronium bromide Oral Solution if you:**")
- anticholinergic medicines (see section above "**DO NOT take Glycopyrronium bromide Oral Solution if you:**")
- antispasmodics used to treat sickness or vomiting e.g. domperidone and metoclopramide
- topiramate used to treat epilepsy
- antihistamines such as promethazine used to treat some allergies
- neuroleptics/antipsychotics (clozapine, haloperidol, phenothiazine), used to treat some mental illnesses
- skeletal muscle relaxants (botulinum toxin)
- antidepressants such as amitriptyline, clomipramine, lofepramine or imipramine (known as tricyclic antidepressants)
- opioids used to treat severe pain
- corticosteroids used to treat inflammatory diseases (e.g. prednisolone).

Talk to your doctor or pharmacist for further information about any medicines to avoid or if you are in doubt about any of the above medicines.

Long term use

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

Pregnancy and breast-feeding

Glycopyrronium bromide Oral Solution must not be given if the patient is pregnant or thinks they may be pregnant or is breastfeeding (see section 2 'Do not take'). Discuss with the patient'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 the performance of skilled tasks such as driving, riding a bicycle, or using machines. If the patient is affected in this way, DO NOT drive, ride a bicycle or operate machinery until their vision and co-ordination have completely recovered. If there is any doubt, ask your doctor for advice.

Glycopyrronium bromide Oral Solution contains:

- **methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216).** These ingredients may cause allergic reactions (possibly delayed).
- **sorbitol.** This medicine contains 375mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. If your doctor told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HF1), 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.
- **propylene glycol.** This medicine contains 150mg propylene glycol in each 5ml dose.
- **sodium.** This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, which is to say essentially 'sodium-free'.
- **ethanol** (present in the cherry flavour); this medicine contains 0.000011mg of alcohol (ethanol) in each 5ml dose. The small amounts of alcohol in this medicine will not have any noticeable effects.

3. HOW TO TAKE GLYCOPYRRONIUM BROMIDE ORAL SOLUTION

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

This medicine is for oral use only and should be given at least **one hour before or two hours after a meal.** If the patient's specific needs determine that co-administration with food is required, it is important to give Glycopyrronium bromide Oral Solution at consistent times in relation to food intake. Do not give this medicine with high-fat foods.

Children and adolescents aged 3 years and older and adults who have suffered from neurological disorders from childhood

Your doctor will decide the correct dose of Glycopyrronium bromide Oral Solution. The initial dose will be calculated based on the weight of the patient. Dose increases will be decided by the patient's 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 (this is why several dose levels appear in the table below). Section 4 includes possible side effects related to the use of Glycopyrronium bromide Oral Solution. These should be discussed with your doctor at all

medical consultations, including those for dose increases and decreases, and at any other time should you be concerned.

The patient should be monitored at regular intervals (at least every 3 months) to check that Glycopyrronium bromide Oral Solution is still the right treatment for you or them.

Glycopyrronium bromide Oral Solution is recommended for short-term intermittent use.

Glycopyrronium bromide 1 mg/5 ml Oral Solution:

Weight	Dose Level 1	Dose Level 2	Dose Level 3	Dose Level 4	Dose Level 5
Kg	ml	ml	ml	ml	ml
14-17	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

Give the dose prescribed by your doctor 3 times each day.

How to use the oral syringe

Remove the child-resistant closure from the bottle. Insert the syringe adaptor with the hole into the neck of the bottle. 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. (Fig. 1) Gently pull down the plunger to the correct level (see the table for the correct dose). Check you have the correct level. The maximum volume of the highest dose is 15ml.

Turn the bottle upright. Remove the oral syringe by holding the bottle and twisting the oral syringe gently. Place the oral syringe inside the patient's mouth and press the plunger slowly to gently release the medicine. Repeat the above steps if a higher dosage (e.g. above 12ml) is recommended for you. After the bottle is turned to the upright position, the dosing syringe can be removed (Fig. 2). Replace the closure after removing the inserted adaptor.

The oral syringe should be washed with warm water and allowed to dry after each use (i.e. three times per day).

Children under 3 years of age MUST NOT take Glycopyrronium bromide Oral Solution.

If you take more Glycopyrronium bromide Oral Solution than you should

If you take more than the prescribed amount of this medicine consult your doctor or get medical advice **immediately**. Always take any leftover medicine with you, as well as the bottle and this leaflet, so that the medical staff know what you have been given.

If you forget to take Glycopyrronium bromide Oral Solution

Do not worry. If you remember later on that day, take that day's dose as usual. If you miss a whole day's dose, take the normal dose on the next day. DO NOT take a double dose to make up for a forgotten dose. If you are not sure, ask your doctor or pharmacist.

If you stop taking Glycopyrronium bromide Oral Solution

Your doctor will tell you how long to take the treatment for. DO NOT stop earlier than you are told, even if you feel better. Your doctor may decide to stop treatment 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, Glycopyrronium bromide Oral Solution can cause side effects, although not everybody gets them.

If any of the following serious side effects occur, **stop using the medicine and seek urgent medical advice.**

- 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

The following side effects may be a sign of a severe allergic reaction. If they occur, take the patient to your 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 secretion in the chest
- Irritability

Common side effects (may affect up to 1 in 10 people)

- Upper respiratory tract infections (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

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

- 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 neurological 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.

Reporting of side effects

If you get 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: 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 bottle label and carton. The expiry date refers to the last day of that month.

After first opening the bottle, Glycopyrronium bromide Oral Solution can be used for **35 days**.

Store in the original package in order to protect from light.

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 Oral Solution contains

The active substance is glycopyrronium bromide. Each 5 ml of Glycopyrronium bromide 1 mg/5 ml Oral Solution contains 1 mg of glycopyrronium bromide.

The other ingredients are citric acid monohydrate, glycerol, methyl parahydroxybenzoate (E218), propylene glycol, propyl parahydroxybenzoate (E216), saccharin sodium, sodium citrate, sorbitol liquid (E420) and cherry flavour (which contains ethanol).

What Glycopyrronium bromide Oral Solution looks like and contents of the pack

Glycopyrronium bromide 1 mg/5 ml Oral Solution is a clear cherry flavoured solution. It is supplied in a 100ml or 150ml amber glass bottle in a cardboard carton. Each carton contains one bottle, one oral syringe and one syringe adaptor.

Marketing Authorisation Holder

Somex Pharma, Ilford, Essex, IG3 8BS. UK.

Manufacturer: Tiofarma B.V., Benjamin Franklinstraat 5-10, 3261 LW Oud-Beijerland, The Netherlands

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Other sources of information

To request a copy of this leaflet in braille or large print, please call 020 8590 9399 (UK Only).



Fig. 1



Fig. 2