

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Glycopyrronium Bromide 1 mg Tablets Glycopyrronium Bromide 2 mg Tablets glycopyrronium bromide

**Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for your child.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Glycopyrronium Bromide Tablets are and what they are used for
2. What you need to know before you give Glycopyrronium Bromide Tablets
3. How to use Glycopyrronium Bromide Tablets
4. Possible side effects
5. How to store Glycopyrronium Bromide Tablets
6. Contents of the pack and other information

#### 1. What Glycopyrronium Bromide Tablets are and what they are used for

This medicine is called Glycopyrronium Bromide 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 muscles or nerves. It is mainly caused by poor control of muscles in the face.

Glycopyrronium Bromide Tablets act on the salivary glands to reduce production of saliva.

#### 2. What you need to know before you give Glycopyrronium Bromide Tablets

##### **Do not give Glycopyrronium Bromide Tablets 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 Tablets),
  - potassium chloride solid dose products
  - anticholinergic medicines

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before giving Glycopyrronium Bromide Tablets 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, pharmacist or nurse before giving Glycopyrronium Bromide Tablets.

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 Tablets 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 Tablets are not recommended for children under 3 years of age.

### **Other medicines and Glycopyrronium Bromide Tablets**

Tell your doctor, pharmacist or nurse 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 Tablets with the following medicines can affect the way Glycopyrronium Bromide Tablets 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 Tablets if the child or adolescent:")
- anticholinergic medicines (see section above "Do not give Glycopyrronium Bromide Tablets 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, pharmacist or nurse for further information about medicines to avoid whilst taking Glycopyrronium Bromide Tablets.

### **Long-term use**

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

### **Pregnancy, breast-feeding and fertility**

This medicine is intended for use in children and adolescents. Glycopyrronium Bromide Tablets 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 Tablets 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 Tablets, 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.

### Information about ingredients of Glycopyrronium Bromide Tablets

This medicine contains Lactose. If you have been told by your doctor that your child has an intolerance to some sugars, contact the doctor before giving this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially ‘sodium-free’.

## 3. How to use Glycopyrronium Bromide Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure. This medicine is for oral use only.

Swallow the tablet with water. The tablet may also be halved along the break-line in order to divide the dose into two equal halves.

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 Tablets and any side effects the child may have. Section 4 includes possible side effects related to the use of Glycopyrronium Bromide Tablets (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 Tablets 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	0.3 mg	0.6 mg	0.9 mg	1.2 mg	1.5 mg
18-22	0.4 mg	0.8 mg	1.2 mg	1.6 mg	2.0 mg
23-27	0.5 mg*	1.0 mg	1.5 mg	2.0 mg	2.5 mg
28-32	0.6 mg	1.2 mg	1.8 mg	2.4 mg	3.0 mg
33-37	0.7 mg	1.4 mg	2.1 mg	2.8 mg	3.0 mg
38-42	0.8 mg	1.6 mg	2.4 mg	3.0 mg	3.0 mg
43-47	0.9 mg	1.8 mg	2.7 mg	3.0 mg	3.0 mg
≥48	1.0 mg	2.0 mg	3.0 mg	3.0 mg	3.0 mg

\* 0.5 mg dose can be achieved by taking ½ of a 1 mg tablet. For doses which cannot be achieved using the tablet formulation, other pharmaceutical forms of glycopyrronium bromide are available.

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

### If you give more Glycopyrronium Bromide Tablets than you should

If you give more of this medicine than the child has been prescribed, side effects are more likely.

Consult the doctor, pharmacist or nurse immediately or go to the emergency department of the nearest

hospital. Always take any remaining tablets 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 Tablets**

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 Tablets**

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, pharmacist or nurse.

### **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 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 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 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 Yellow Card Scheme website: [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 Tablets**

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.

This medicine does not require any special storage conditions.

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 Tablets contain**

- The active substance is glycopyrronium bromide.
- The other ingredients are lactose anhydrous, calcium hydrogen phosphate dihydrate, copovidone, sodium starch glycolate and magnesium stearate.

### **What Glycopyrronium Bromide Tablets look like and contents of the pack**

Glycopyrronium Bromide 1 mg Tablets are white to off-white, round, scored, uncoated tablet, debossed with 'WM' and '1' on either side of score line on one side and plain on other side.

Glycopyrronium Bromide 2 mg Tablets are white to off-white, round, scored, uncoated tablet, debossed with 'WM' and '2' on either side of score line on one side and plain on other side.

Tablets are supplied in PVC/Alu or Alu-Alu blisters with pack sizes of 10, 14, 28, 30, 56, 60, 90 and 112 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

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Sovereign House,  
Miles Gray Road, Basildon,  
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### **Manufacturer**

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**This leaflet was last revised in 02/2025.**

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