

# GLYCOPYRROLATE ACCORD INJECTION

*Glycopyrronium bromide (glycopyrrolate), solution for injection, 0.2 mg/1 mL and 0.6 mg/3 mL*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about Glycopyrrolate Accord. It does not contain all the available information

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Glycopyrrolate Accord against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

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### What Glycopyrrolate Accord Injection is used for

#### *When you must not be given it*

Do not have Glycopyrrolate Accord if:

You are allergic to Glycopyrrolate Accord or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

You are breastfeeding or plan to breastfeed.

Medicines like Glycopyrrolate Accord may reduce your milk supply. It is not known if Glycopyrrolate Accord is found in breast milk.

Do not have Glycopyrrolate Accord if the packaging is torn or shows signs of tampering.

Do not have Glycopyrrolate Accord after the expiry date (EXP.) printed on the pack.

If you have it after the expiry date has passed, it may not work as well.

#### *Before you are given it*

#### **You must tell your doctor if:**

##### **1. You have any allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

##### **2. You are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of receiving Glycopyrrolate Accord during pregnancy.

##### **3. You have or have had any other medical conditions including:**

- asthma
- glaucoma, which is an increased pressure in your eyes
- diarrhoea
- problems with your heart, kidney or thyroid
- difficulty urinating, or enlarged prostate
- stomach or bowel problems

- hiatus hernia that causes heartburn and belching
- high blood pressure
- myasthenia gravis, a muscle weakness disorder
- nerve or brain disorder, brain damage, or Down's Syndrome.

**If you have not told your doctor about any of the above, tell them before you are given Glycopyrrolate Accord.**

#### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with Glycopyrrolate Accord. These include:

- ritodrine hydrochloride
- medicines for Parkinson's disease
- phenothiazines, which are used to treat mental illness or severe nausea and vomiting
- antidepressants
- antihistamines
- narcotic pain killers such as pethidine
- medicines used to control heart rhythm
- digoxin used to treat heart failure
- thioxanthenes
- butyrophenones
- amantadine.

These medicines may be affected by Glycopyrrolate Accord or may affect how well it works. You may

need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid when given Glycopyrrolate Accord.

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## How Glycopyrrolate Accord Injection is given

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### *How much is given*

A doctor gives Glycopyrrolate Accord to you.

The dose of Glycopyrrolate Accord may be different for each person. The dose given depends on your condition, age, body weight and your doctor. Your doctor will decide the right dose for you. For children aged 1 month to 12 years, the usual dose depends on their bodyweight.

When used before surgery the usual adult dose is 0.2 to 0.4 mg given by injection into either a vein or a muscle. You will get Glycopyrrolate Accord before the anaesthetic is given.

For use during surgery, the usual adult dose is a single injection of 0.2 to 0.4 mg into a vein. Sometimes the dose may need to be repeated. Your doctor will decide if this needs to happen.

To counter the effects of other medicines, the usual adult dose of Glycopyrrolate Accord is 0.2 mg per 1 mg neostigmine or the equivalent dose of pyridostigmine given by injection into a vein.

### *How it is given*

A doctor gives Glycopyrrolate Accord to you. The injection is usually given into a muscle or a vein. If GLYCOPYRROLATE ACCORD is given to counter the effects of other medicines, it may be

given in the same syringe as the neostigmine or pyridostigmine.

### *How long is it given*

Glycopyrrolate Accord is usually given as a single dose, but sometimes a dose must be repeated. Your doctor will decide how many doses of Glycopyrrolate Accord are needed.

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## While you are having Glycopyrrolate Accord Injection

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### *Things you must do*

**Tell any other doctors, dentists and pharmacists who are treating you that you have had Glycopyrrolate Accord.**

**Tell your doctor if you feel Glycopyrrolate Accord is not helping your Condition**

**Always discuss with your doctor any problems or difficulties during or after having Glycopyrrolate Accord.**

### *Things you must not do*

**Do not drive or operate machinery until you know how Glycopyrrolate Accord affects you.**

Glycopyrrolate Accord may cause drowsiness or dizziness or blurred vision in some people and therefore may affect alertness.

Make sure you know how you react to Glycopyrrolate Accord before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

### *Things to be careful of*

**Be careful if you are elderly, unwell or taking other medicines.**

Some people may experience side effects such as drowsiness, or blurred vision, which may increase the risk of a fall.

**Be careful during warm weather and temperature, and/or with physical exercise after use of Glycopyrrolate Accord. Glycopyrrolate Accord may reduce your ability to sweat and can therefore cause overheating.**

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Glycopyrrolate Accord.**

Glycopyrrolate Accord helps most people with your condition, but it may have unwanted side effects in some people.

All medicines may have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- fast, slow or irregular heart beats
- flushing
- unable to sweat
- feeling sick or vomiting
- dry mouth
- dry and/or itchy skin
- constipation
- difficulty urinating
- impotence
- reduced milk supply in breastfeeding women
- blurred vision or other problems with your eyesight
- headache
- nervousness, drowsiness
- dizziness
- unable to sleep
- over-excitement in children
- confusion, especially in elderly people
- fever
- feeling bloated

- loss or alteration of taste

These side effects are usually mild.

Rare side effects include: injection site reactions like itchy skin, swelling, pain.

**Tell your doctor immediately if you notice any of the following:**

- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- cold sweat, nausea, light headedness, discomfort in chest or other areas of the upper body like pain or discomfort in one or both arms, the back, neck, jaw or stomach

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

**Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking, Glycopyrrolate Accord.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## Storage

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Glycopyrrolate Accord will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

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## Product description

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### *What it looks like*

Glycopyrrolate Accord comes in a clear glass ampoule containing a clear, colourless solution. Each ampoule is for single use in one

patient only. Discard any remaining residue.

Glycopyrrolate Accord is available in the following strengths and pack sizes:

- 0.2 mg/1 mL, packs of 5 and 10 ampoules
- 0.6 mg/3 mL, packs of 5 and 1 ampoules.

Not all presentations may be marketed.

### *Ingredients*

The active ingredient in Glycopyrrolate Accord is glycopyrronium bromide (glycopyrrolate). Each ampoule contains 0.2 mg/mL of glycopyrronium bromide (glycopyrrolate).

Glycopyrrolate Accord also contains:

- sodium chloride
- hydrochloric acid
- water for injections.

Glycopyrrolate Accord does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

### *Name and Address of the Sponsor*

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne, VIC, 3000  
Australia

### **Australian Registration Numbers**

0.2 mg/1 mL: AUST R 237760

0.6 mg/3 mL: AUST R 237403

### **Date of Preparation**

This leaflet was prepared on 11 May 2020.