

Package leaflet: Information for the user
Glycopyrronium Bromide 200 micrograms/ml Solution for Injection

Read all of this leaflet carefully before you start using 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 nurse.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This product will be referred to as Glycopyrronium Injection from here on.

What is in this leaflet:

1. What Glycopyrronium Injection is and what it is used for
2. What you need to know before you use Glycopyrronium Injection
3. How to use Glycopyrronium Injection
4. Possible side effects
5. How to store Glycopyrronium Injection
6. Contents of the pack and other information

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

Glycopyrronium bromide belongs to a group of medicines called anticholinergic drugs.

Glycopyrronium Injection may be used:

- To protect against some of the unwanted effects of drugs such as neostigmine or pyridostigmine, which are used to reverse the effects of certain types of muscle-relaxing drugs (called non-depolarising muscle relaxants).
- Before an operation, to reduce saliva and other secretions and to reduce the acidity of the stomach contents.
- Before or during an operation, to reduce or prevent slowing of the heartbeat during surgery.

2. What you need to know before you use Glycopyrronium Injection

Do not use Glycopyrronium Injection:

- if you are allergic to Glycopyrronium bromide or any other ingredients of this medicine (listed in section 6).
- if you have glaucoma (increased pressure in the eye)
- if you suffer from myasthenia gravis (a disorder that causes extreme muscle weakness and fatigue)
- if you have stomach or bowel problems such as obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus)
- if you have a prolonged QT interval (irregular heart rhythm) and have also received an antimuscarinic such as neostigmine.
- if you have an enlarged prostate gland.

Warnings and precautions

Talk to your doctor or nurse before using **Glycopyrronium Injection**

- if you have Down's Syndrome
- if you are over 60 years of age
- if you are a child

- if you have just had a heart attack
- if you suffer from asthma or attacks of wheezing
- if you suffer from cardiac arrhythmia (irregular heart beats) or slow heart rate
- if you suffer from epilepsy or Parkinsonism (A disorder of the brain causing muscle stiffness and shaking)
- if you have a condition characterised by rapid heart beat (including over-active thyroid, heart failure or heart surgery)
- if you are pregnant or breast-feeding
- if you have a history of high blood pressure, coronary artery disease or irregular heart beats
- if you are receiving inhalation anaesthesia (to put you asleep before an operation, using medicines such as cyclopropane or halothane) as it may cause a change in your normal heart rhythm
- if you have gastric reflux (a condition in which the liquid stomach contents backs up (regurgitates) into the gullet)
- if you have diarrhoea
- if you have ulcerative colitis (a chronic inflammation of the large intestine (colon) which can cause abdominal pain, diarrhoea and bleeding from the back passage)
- if you have had a recent operation on the intestines (gut)
- if you have a high temperature (as the drug will inhibit sweating).

Avoid repeated or large doses if you have kidney disease.

Other medicines and Glycopyrronium Injection

Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines. A large number of drugs can interact with Glycopyrronium Injection which can significantly alter their effects. These drugs include:

- drugs for depression known as Tricyclic antidepressants (for example amitriptyline or imipramine) and Monoamine Oxidase Inhibitors (MAOIs) (for example phenelzine, tranylcypamine).
- clozapine which is used to treat severe mental disorders.
- nefopam which is used as a pain-killer.
- amantadine and levodopa which is used to treat Parkinson's disease or viral infection.
- phenothiazines used to treat severe mental problems or nausea, vomiting or vertigo (for example chlorpromazine, fluphenazine, prochlorperazine, trifluoperazine).
- antihistamines used to treat allergies (for example promethazine).
- nefopam (used to treat acute and chronic pain).
- pethidine (used to treat moderate to severe pain).
- domperidone or metoclopramide (used to treat nausea and vomiting).
- ketoconazole (used to treat fungal infections).
- memantine (used to treat Alzheimer's disease).
- parasympathomimetics (these are drugs that affect chemicals in the body which are involved in transmission of nerve impulses to a muscle) (for example carbachol, neostigmine, physostigmine).
- ritodrine (used to prevent uncomplicated premature labour).
- corticosteroids used to treat various conditions including asthma and inflammatory disease (for example prednisolone).
- slow-dissolving digoxin tablets, disopyramide (used to treat heart problems).
- may increase the heart rate when used with a class of drugs known as sympathomimetics (commonly present in cough and cold preparations and weight reducing medicines).
- Glyceryl trinitrate tablets (used to treat angina) may not dissolve under the tongue as well as usual owing to the dry mouth which glycopyrronium bromide causes.

Pregnancy, breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.

Glycopyrronium Injection should be given during pregnancy only if considered essential by your doctor.

Driving and using machines

Do not drive or use machines because this medicine can cause blurred vision, dizziness and other effects that may affect your ability to do so.

Do not drive or use machinery until these effects have gone or until your doctor advises you that you are safe to do so.

Glycopyrronium Injection contains sodium

This injection contains less than 1mmol (23mg) of sodium per 2 ml (essentially 'sodium-free').

3. How to use Glycopyrronium Injection

Glycopyrronium Injection is administered by injection into a vein or muscle.

Your doctor will decide the correct dose for you depending on your circumstances. Your dose may be calculated according to your weight.

The injection may need to be repeated depending on your response.

The recommended dose is:

Dosage when used before an operation

Adults and elderly

200 to 400 micrograms (0.2 to 0.4mg) may be injected into a vein or into a muscle before the anaesthetic is given. Alternatively, a dose of 4 to 5 micrograms per kilogram of body weight (0.004 to 0.005mg per kg) may be used, up to a maximum dose of 400 micrograms (0.4mg).

Use in children and adolescents:

4 to 8 micrograms per kilogram of body weight (0.004 to 0.008mg per kg) up to a maximum of 200 micrograms (0.2mg) may be injected into a vein or into a muscle before the anaesthetic is given.

Dosage when used during an operation

Adults and elderly

A single dose of 200 to 400 micrograms (0.2 to 0.4mg) should be given by injection into a vein. Alternatively, a single dose of 4 to 5 micrograms per kilogram of body weight (0.004 to 0.005mg per kg) may be used, up to a maximum of 400 micrograms (0.4mg). This dose may be repeated if necessary.

Use in children and adolescents

A single dose of 200 micrograms (0.2mg) should be given by injection into a vein. Alternatively, a single dose of 4 to 8 micrograms per kilogram of body weight (0.004 to 0.008mg per kg) may be used, up to a maximum of 200 micrograms (0.2mg). This dose may be repeated if necessary.

Dosage when reversing the effects of non-depolarising muscle relaxants

Adults and elderly:

200 micrograms (0.2mg) per 1,000 micrograms (1mg) of neostigmine or the equivalent dose of pyridostigmine, by injection into a vein.

Alternatively, a dose of 10 to 15 micrograms per kilogram of body weight (0.01 to 0.015mg per kg) may be injected into a vein with 50 micrograms per kg (0.05mg per kg) of neostigmine or equivalent dose of pyridostigmine. Glycopyrrolate Injection may be administered at the same time and from the same syringe with the neostigmine or pyridostigmine.

Use in children and adolescents

10 micrograms per kg of body weight (0.01mg per kg) may be injected into a vein with 50 micrograms per kg (0.05mg per kg) of neostigmine or the equivalent dose of pyridostigmine. Glycopyrrolate Injection may be administered at the same time and from the same syringe with the neostigmine or pyridostigmine.

Dosage in patients with impaired kidney function:

If you have impaired kidney function, your doctor will decide upon a dose that suits your condition.

If you have been given more Glycopyrrolate Injection than you should

This is unlikely because the dose will be administered by a healthcare professional. If you suspect you have been given too much, you should tell your doctor immediately.

If you have any further questions on the use of this medicine ask your doctor or nurse.

4. Possible side effects

Like all medicines this medicine can cause side-effects, although not everybody gets them.

Consult a doctor straight away if you notice any of the following symptoms - you may need urgent medical treatment:

Swelling mainly of the face, lips or throat which makes it difficult to swallow or breathe, itching and rashes. This could be a sign of a severe allergic reaction or angioedema (frequency not known, cannot be estimated from the available data).

All medicines can cause allergic reactions although serious allergic reactions are very rare.

The following side effects have also been reported but their frequency is unknown:

- a dry mouth
- difficulty in passing water (urinating)
- inability to completely or partially empty the bladder
- blurred vision
- visual disturbances
- enlarged pupils with loss of focus
- reduced ability to sweat
- a faster heart rate than normal
- changes in heart rate (fast/irregular heartbeats)
- slow heart rate
- palpitations (an awareness of strong, thumping heart beats)
- difficulty in passing stools (constipation)
- reduced lung secretion
- fear of bright light
- redness and dryness of the skin
- confusion may occur in elderly
- drowsiness
- feeling sick (nausea)
- vomiting

- feeling giddy
- glaucoma (increased pressure in the eyes).

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:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
email: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glycopyrronium Injection

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 label and carton.

The expiry date refers to the last day of that month.

Do not store above 25°C.

If only part used, discard the remaining solution. The injection should not be used if particles are present.

Do not use this medicine if you notice the ampoule is damaged or if the contents are discoloured.

Do not throw away 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 Injection contains

The active substance is Glycopyrronium Bromide.

The other ingredients are sodium chloride, dilute hydrochloric acid and water for injections.

What Glycopyrronium Injection looks like and contents of the pack

Glycopyrronium Injection is a clear, colourless, sterile solution for injection.

Each 1ml glass ampoule contains 200 micrograms (0.2mg) of glycopyrronium bromide.

Each 3ml glass ampoule contains 600 micrograms (0.6mg) of glycopyrronium bromide.

Each carton contains ten 1ml ampoules or three or ten 3ml ampoules of Glycopyrronium Injection.

Marketing Authorization Holder

MercuryPharm Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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