

Glycopyrronium Bromide 200 micrograms/ml Solution for Injection

Glycopyrronium Bromide
(referred to as Glycopyrronium Injection in this leaflet)

Read all of this leaflet carefully before you are given 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, 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 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 Injection contains the active substance glycopyrronium bromide.

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

You should not be given Glycopyrronium Injection if:

- you are allergic to glycopyrronium bromide or to any of the other ingredients in 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 an enlarged prostate;
- if you have stomach or bowel problems.
- If you suffer from a prolonged QT interval (irregular heart rhythm) should avoid the combination use of neostigmine plus glycopyrronium.

Warnings and precautions

Take special care with Glycopyrronium Injection. Tell your doctor if:

- 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 have a condition characterised by rapid heartbeat (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 heartbeats;
- if you are receiving inhalation anaesthesia (to put you asleep before an operation) 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 a high temperature (as the drug will inhibit sweating).
- avoid repeated or large doses if you suffer from renal impairment (kidney problems), and your doctor may adapt the dose accordingly.

Always **tell your doctor or nurse** about any of these conditions before having your injection.

Other medicines and Glycopyrronium Injection

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Medicines which may interact with Glycopyrronium Injection include:

- drugs for depression known as Tricyclic Antidepressants for example amitriptyline or imipramine and Monoamine Oxidase Inhibitors (MAOIs) for example phenelzine, tranylcypamine);
- clozapine (used to treat schizophrenia);
- 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);
- amantadine, levodopa (used to treat Parkinson's disease);
- memantine (used to treat Alzheimer's disease);
- parasymphomimetics (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.

Glycerol 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 for advice before being given this medicine.

Driving and using machines.

After having Glycopyrronium Injection you should not drive or operate 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.

Glycopyrronium Injection contains sodium

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

3. How to use Glycopyrronium Injection

Glycopyrronium Injection is given by injection into a muscle (intramuscularly) or into a vein (intravenously).

Dosage when used before an operation:

Adults, adolescents over 12 years old and elderly patients:

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

Children:

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

Continued overleaf

Dosage when used during an operation:

Adults, adolescents over 12 years old and elderly patients:

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

Children:

The recommended single dose of 200 micrograms (0.2mg)

by injection into a vein.

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

If you are given too much Glycopyrronium Injection

This medicine will be given to you in hospital so it is unlikely you will receive too much, however if you are concerned you may have been given too much you should speak to your doctor or nurse. If you have any further questions about this medicine, ask your doctor or nurse.

Dosage when reversing the effects of non-depolarising muscle relaxants:

Adults, adolescents over 12 years old and elderly patients:

Your doctor will give you 200 micrograms (0.2mg) per 1,000 micrograms (1mg) of Neostigmine or the equivalent dose of pyridostigmine, by injection into a vein. Alternatively, they may give you a dose of 10 to 15 micrograms per kilogram of body weight (0.01 to 0.015 mg per kg) into a vein with 50 micrograms per kg (0.05 mg per kg) of neostigmine or equivalent dose of pyridostigmine.

Glycopyrronium Injection may be given at the same time and from the same syringe as the neostigmine or pyridostigmine.

Children:

Your doctor may give your child 10 micrograms per kg of body weight (0.01mg per kg) injected into a vein with 50 micrograms per kg (0.05mg per kg) of neostigmine or the equivalent dose of pyridostigmine. Glycopyrronium Injection may be given at the same time and from the same syringe as 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.

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).

Tell your doctor or nurse if you notice any of the following symptoms:

- slow heart rate
- confusion may occur in the elderly;
- a need to pass water often than usual;
- feeling sick (nausea);
- vomiting;
- giddiness;
- flushing and dryness of the skin;
- enlarged pupils with loss of focus;
- intolerance to light;
- constipation;
- absence of sweating;
- reduced bronchial secretions;
- high pressure in the eye.

Very common side effect (affects more than 1 in 10 people):

- dry mouth

Common (may affect up to 1 in 10 people)

- drowsiness
- visual disturbances
- changes in heart rate (fast/irregular heartbeats)
- urge to pass water but inability to do so

Very rare (may affect up to 1 in 10,000 people)

- increase pressure in the eye (glaucoma).

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: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glycopyrronium Injection

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions. 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.

If only part of an ampoule is used the remaining solution should be discarded. 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 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 Injection contains.

The **active substance** is Glycopyrronium Bromide.

Each 1ml glass ampoule contains 200 micrograms of glycopyrronium bromide.

Each 3ml glass ampoule contains 600 micrograms of glycopyrronium bromide.

The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment) and water for injections.

What Glycopyrronium Injection looks like and contents of the pack.

Glycopyrronium Injection is a clear, colourless solution for injection. Glycopyrronium Injection is available in glass ampoules containing either 1ml or 3ml of solution. Each carton supplied contains 10 ampoules.

Marketing Authorisation Holder

Martindale Pharmaceuticals Limited, Bampton Road, Harold Hill, Romford, Essex, RM38UG, UK

Manufacturer

Macarthy's Laboratories Ltd.
Trading as Martindale Pharma, Bampton Road, Harold Hill Romford, Essex, UK

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Bampton Road, Harold Hill, Romford, RM3 8UG, UK