

Glycopyrronium Bromide and Neostigmine Metilsulfate 0.5mg/2.5mg per ml Solution for Injection

Glycopyrronium Bromide
Neostigmine Metilsulfate
(referred to as Glycopyrronium and Neostigmine Injection in this leaflet)

Read 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, pharmacist 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 and Neostigmine Injection is and what it is used for
2. What you need to know before you are given Glycopyrronium and Neostigmine Injection.
3. How Glycopyrronium and Neostigmine Injection is given.
4. Possible side effects.
5. How to store Glycopyrronium and Neostigmine Injection.
6. Contents of the pack and other information

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

Glycopyrronium-Neostigmine Injection contains two active ingredients:

- Glycopyrronium Bromide belongs to a group of medicines called anticholinergic drugs. It is used to counteract some unwanted effects that may occur with Neostigmine.
- Neostigmine belongs to a group of medicines called cholinesterase inhibitors. It can be used to reverse the effects of a type of muscle-relaxing drug used during operations called non-depolarising muscle relaxants.

Glycopyrronium and Neostigmine Injection is used to reverse the muscle relaxation produced by non-depolarising muscle relaxants.

2. What you need to know before you are given Glycopyrronium and Neostigmine Injection.

You should not be given Glycopyrronium and Neostigmine Injection if:

- you are allergic to Glycopyrronium Bromide or Neostigmine Metilsulfate, or to any of the other ingredients in this medicine, (listed in section 6).
- you think you may have a blockage in your intestine or urinary passage.
- you have been given suxamethonium, a drug used to relax your muscles during surgery.

Warnings and precautions

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

- you are pregnant or breast feeding;
- you suffer from glaucoma (increased pressure in the eye);
- you have had a recent operation on your intestines;
- you suffer from stomach ulcers;
- you suffer from asthma attacks, wheezing or difficulty breathing;
- you have a very slow heart beat (less than 60 beats per minute) or you are suffering from coronary artery disease; heart failure, irregular heartbeats or high or low blood pressure;

- you have recently suffered a heart attack;
- you have an overactive thyroid gland;
- you suffer from kidney problems;
- you suffer from myasthenia gravis (a disease resulting in severe muscle weakness and fatigue);
- you are suffering from epilepsy or Parkinson's;
- you have a fever;
- you suffer from enlarged prostate gland;
- you suffer from obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus);
- you are under the influence of anaesthetics like Cyclopropane or Halothane.

Other medicines and Glycopyrronium and Neostigmine 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 and Neostigmine Injection include:

- suxamethonium, a drug used to relax your muscles during surgery;
- medicines used to treat bacterial infections known as aminoglycoside antibiotics, such as gentamicin and streptomycin;
- medicines used to treat bacterial infections known as polymyxins, such as colistimethate sodium;
- clindamycin, a medicine used to treat bacterial infections;
- medicines used to treat an irregular heartbeat, such as procainamide, propafenone and quinidine;
- chloroquine, a medicine used to treat and prevent malaria;
- lithium, a medicine used to treat bipolar disorder;
- medicines used to relax your muscles during surgery known as non-depolarising muscle relaxants
- propranolol, a medicine used to treat a number of conditions including migraines, heart problems and anxiety
- a type of medicine used to dry body secretions during surgery, known as antimuscarinics
- medicines to treat depressions (e.g. Tricyclic Antidepressant, MAOIs)
- Amantadine which is used to treat Parkinson's disease or viral infections
- medicines used to treat mental illness (e.g. Nefopam)

Important information about some of the other ingredients in Glycopyrronium-Neostigmine Injection

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

Pregnancy, breast-feeding and fertility.

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 and Neostigmine Injection you should not drive or operate machinery until you have been advised that it is safe to do so because it can cause blurred vision and other effects that may affect your ability to do so. Do not drive or use machinery until these effects have gone

3. How Glycopyrronium and Neostigmine Injection is given.

Glycopyrronium and Neostigmine Injection is given by injection into a vein.
Your doctor will decide the correct dose for you depending on your circumstances. Your dose may be calculated according to your weight.

Continued overleaf

Recommended dose:

Adults and elderly patients:

Your doctor will inject 1-2ml into a vein over a period of 10 to 30 seconds. Alternatively, your doctor may inject a dose of 0.02ml per kg body weight into a vein over a period of 10 to 30 seconds, up to a maximum of 2ml.

Paediatric patients:

Your doctor will inject 0.02ml per kg body weight into a vein over a period of 10 to 30 seconds, up to a maximum of 2ml.

If you are given too much Glycopyrronium and Neostigmine Injection

This medicine will be given to you in hospital so it is unlikely you will receive too much, however if you experience any of the following symptoms you should tell your doctor or nurse **immediately:**

- difficulty breathing
- you have too much saliva or increased sweating
- watering eyes or pinpoint pupils
- losing control of your bowels or bladder
- an unusually fast or slow or irregular heartbeat, or low blood pressure (you may feel faint)
- feeling agitated or an increase in the amount you dream
- weakness, muscle twitching or paralysis

If you have any further questions about 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).

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

- a dry mouth;
- difficulty in passing urine;
- blurred vision;
- absence of sweating;
- a very slow heartbeat, palpitations or irregular heartbeats;
- too much saliva;
- wheeziness;
- stomach cramps, feeling sick (nausea), or being sick (vomiting);
- diarrhoea;
- hypotension;
- intolerance to light;
- weakness;
- increased lung secretions;
- increased secretions of stomach;
- increased sweating;
- confusion;
- increased pressure in 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Glycopyrronium and Neostigmine Injection.

Keep out of the sight and reach of children.
Do not store above 25°C. Keep the container in the outer carton to protect from light.

You should not be given this medicine after the expiry date which is stated on the label and carton after EXP, or if it shows signs of deterioration. The expiry date refers to the last day of that month. The doctor or nurse will check this.

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

6. Contents of the pack and other information

What Glycopyrronium and Neostigmine Injection contains.

The **active substances** are Glycopyrronium Bromide and Neostigmine Metilsulfate. Each 1ml of Glycopyrronium and Neostigmine Injection contains 0.5mg of Glycopyrronium Bromide and 2.5mg of Neostigmine Metilsulfate. The **other ingredients** are sodium phosphate, citric acid monohydrate, citric acid solution, sodium hydroxide and water for injections.

What Glycopyrronium and Neostigmine Injection looks like and contents of the pack.

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

Glycopyrronium and Neostigmine Injection is available in glass ampoules each containing 1ml of solution. Each carton supplied contains ten 1ml ampoules.

Marketing Authorisation Holder and Manufacturer

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