

Package leaflet: Information for the user
Glycopyrronium Bromide and Neostigmine
Metilsulfate 0.5mg/2.5mg per ml Solution for Injection

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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This product is known by the above name but will be referred to as Glycopyrronium-Neostigmine Injection throughout the rest of this leaflet.

What is in this leaflet

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

1. WHAT GLYCOPYRRONIUM-NEOSTIGMINE INJECTION IS AND WHAT IT IS USED FOR

Glycopyrronium-Neostigmine Injection contains two active ingredients:

- Neostigmine which belongs to a group of medicines called cholinesterase inhibitors. It has the effect of reversing the action of certain muscle-relaxing drugs.
- Glycopyrronium Bromide which belongs to a group of medicines called anticholinergic drugs. Its purpose is to block some of the unwanted effects that may occur with Neostigmine such as slowing the heart rate or excess production of saliva.

Glycopyrronium-Neostigmine Injection is used at the end of an operation to reverse the effects of some of the drugs used during surgery such as anaesthetics and muscle relaxants.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN GLYCOPYRRONIUM-NEOSTIGMINE INJECTION

Do not use Glycopyrronium-Neostigmine Injection:

- if you are allergic to Glycopyrronium Bromide or Neostigmine or any of the other ingredients of this medicine (listed in section 6).
- if you are also receiving Suxamethonium, a muscle relaxant usually given during operations.
- if you think you may have a blockage in your intestine or urinary passage.
- Anticholinesterase-antimuscarinic combinations such as neostigmine plus glycopyrronium should be avoided in patients with a prolonged QT interval (irregular heart rhythm).

Warnings and precautions

Talk to your doctor or nurse before you are given Glycopyrronium-Neostigmine Injection

- if you suffer from asthma attacks, wheezing or difficulty in breathing
- if you suffer from glaucoma (Increased pressure in the eye)
- if you have had a recent operation on the intestines (Gut)
- if you suffer from stomach ulcers
- if you have a high temperature (fever)
- if you have low or high blood pressure
- if you suffer from cardiac arrhythmia (irregular heart beats) or slow heart rate (less than 60 beats per minute) or you are suffering from coronary artery disease
- if you suffer from coronary artery disease, a heart attack, heart failure or heart disease
- if you are under influence of anaesthetics like Cyclopropane or Halothane
- if you have an overactive thyroid gland
- if you are suffering from epilepsy or Parkinsonism (A disorder in the brain causing muscle stiffness and shaking)
- if you suffer from myasthenia gravis (a disease resulting in severe muscle weakness and fatigue)
- if you have an enlarged prostate gland
- if you suffer from obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus)
- if you suffer from kidney problems
- if you have disorder resulting from overstimulation of the vagus nerve, causing a slowing of the heart rate, fainting, constipation and sweating
- if you are pregnant or breast feeding

Glycopyrronium bromide should be used with caution in children and elderly people.

Other medicines and Glycopyrronium-Neostigmine Injection

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

This is especially important with the following medicines as they may interact with Glycopyrronium-Neostigmine Injection:

- medicines to treat depression (e.g. Tricyclic Antidepressant for example amitriptyline or imipramine, MAOI's for example phenelzine, tranylcypamine)
- medicine used to treat mental illness (e.g. Clozapine)
- medicine used to relieve the pain (e.g. Nefopam)
- Amantadine which is used to treat Parkinson's disease or viral infection
- Suxamethonium, a muscle relaxant usually given during operations
- 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

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 using this medicine.

Driving and using machines

This medicine may cause your eyesight to become weak and this could interfere with your ability to drive or operate machinery safely.

Ask your doctor for advice before you drive or operate machinery.

Glycopyrronium-Neostigmine Injection contains sodium

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

3. HOW GLYCOPYRRONIUM-NEOSTIGMINE INJECTION IS GIVEN TO YOU

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Glycopyrronium-Neostigmine Injection is administered by injection into a vein.

The recommended dose is

Adults and elderly: 1-2 ml injected into a vein over a period of 10 to 30 seconds.

Alternatively, a dose of 0.02 ml per kg body weight may be injected into a vein over a period of 10 to 30 seconds.

Use in Children: 0.02ml per kg body weight may be injected into a vein over a period of 10 to 30 seconds.

Your doctor will decide the correct dose for you depending on your circumstances.

Your dose may be calculated according to your weight.

The injection is usually given over a period of 10-30 seconds, and may need to be repeated depending on your response.

If you have been given more Glycopyrronium-Neostigmine Injection than you should

This is unlikely because the dose will be administered by a health professional. An overdose may cause changes in the speed of heart rate, increased production of saliva and difficulty in breathing.

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. All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

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

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

The following side effects have also been reported but their frequency is not known:

- dry mouth
 - difficulty in passing stools (Constipation)
 - a very slow heart rate (Bradycardia)
 - an awareness of strong, thumping heart beats (Palpitation) or irregular heart beats (could be related to either glycopyrrolate or neostigmine)
 - reduced secretion in lungs
 - difficulty in passing urine
 - inability to completely empty the bladder (urinary retention)
 - uncontrollable urge to pass urine
 - visual disturbances
 - increased sensitivity of the skin to light (Photophobia)
 - enlargement of pupil
 - glaucoma (increased pressure in the eye)
 - absence of sweating
 - dryness of the skin
 - reddening of the skin and other areas of the skin (Flushing)
 - confusion
 - nausea (feeling sick)
 - vomiting (being sick), dizziness
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- increased secretions of stomach • increase in mucus secretion
 - too much saliva
 - tummy cramps
 - diarrhea

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 at: Website: 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-NEOSTIGMINE 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 carton and ampoule label after 'Exp date'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the ampoules in the outer carton in order to protect from light.

Once opened, use immediately.

If only part used, discard the remaining solution.

Do not dilute.

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-Neostigmine Injection contains

The active substances are Glycopyrronium bromide and Neostigmine metilsulfate.

Each glass ampoule contains 1 ml of solution, which contains the two active ingredients glycopyrronium bromide 0.5mg and neostigmine metilsulfate 2.5mg.

The other ingredients are disodium phosphate dodecahydrate, citric acid monohydrate, citric acid solution or sodium hydroxide (for pH adjustment) in water for injections.

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

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

Each carton contains ten 1ml ampoules of Glycopyrronium-Neostigmine Injection.

Marketing authorization holder

Mercury Pharmaceuticals Ltd

Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer

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

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