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 Bromide and Neostigmine Metilsulfate Injection throughout the rest of this leaflet.

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

1. WHAT GLYCOPYRRONIUM BROMIDE AND NEOSTIGMINE METILSULFATE INJECTION IS AND WHAT IT IS USED FOR

Glycopyrronium Bromide and Neostigmine Metilsulfate Injection contains two active ingredients:
• Neostigmine Metilsulfate 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 Metilsulfate such as slowing the heart rate or excess production of saliva.
Glycopyrronium Bromide and Neostigmine Metilsulfate 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 BROMIDE AND NEOSTIGMINE METILSULFATE INJECTION

Do not use Glycopyrronium Bromide and Neostigmine Metilsulfate Injection:
• if you are allergic to Glycopyrronium Bromide or Neostigmine Metilsulfate or any of the other ingredients of this medicine (listed in section 6)
• if you have a blockage in your stomach, intestine or urinary passages such as bladder or kidneys
• if you are also receiving suxamethonium, a muscle relaxant usually given during operations.
Make sure your doctor knows if you suffer from any of the above.

Warnings and precautions
Talk to your doctor or nurse before you are given Glycopyrronium Bromide and Neostigmine Metilsulfate Injection
• if you suffer from asthma or attacks of wheezing
• 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 increased body temperature (especially children)
• if you have high blood pressure

• if you suffer from cardiac arrhythmia (irregular heart beats) or slow heart rate
• if you suffer from heart failure or heart disease
• if you are under influence of anaesthetics like Cyclopropane or Halothane
• if you suffer from myasthenia gravis (leading to muscle weakness and fatigue)
• if you have an enlarged prostrate gland
• if you suffer from obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus)
• 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).

Other medicines and Glycopyrronium Bromide and Neostigmine Metilsulfate Injection
Tell your doctor if you are taking, have recently taken, or might take any other medicines
• medicines to treat depression (e.g. Tricyclic Antidepressant, MAOI's- Monoamine oxidase inhibitors)
• 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.

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

3. HOW GLYCOPYRRONIUM BROMIDE AND NEOSTIGMINE METILSULFATE 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.

The recommended dose is:

For Adults and elderly patients: your doctor will inject 1 – 2ml intravenously over a period of 10 to 30 seconds. Alternatively, your doctor will administer a specific dose based on your body weight (i.e. 0.02 ml/kg) over a period of 10-30 seconds.

Paediatric population: Alternatively, your doctor will administer a specific dose based on your body weight (i.e. 0.02ml/kg) 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 Bromide and Neostigmine Metilsulfate 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 suspect you have been given too much, you should tell the 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.
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)
• slow heart rate (Bradycardia)
• an awareness of strong, thumping heart beats (Palpitation) or irregular heart beats
• reduced secretion in lungs
• difficulty in passing urine
• increased sensitivity of the skin to light (Photophobia)
• dryness of the skin
• reddening of the skin (Flushing)
• confusion
• nausea (Feeling sick), vomiting (Being sick), dizziness
• increased pressure in the eye (Glaucoma)
• dilated pupils
• blurred vision
• increased secretions of stomach and inhibition/decreased sweating.

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
E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GLYCOPYRRONIUM BROMIDE AND NEOSTIGMINE METILSULFATE 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 use this medicine if you notice the ampoule is damaged or if the contents are discoloured or deteriorated.
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 Bromide and Neostigmine Metilsulfate Injection contains

- The active substances are Glycopyrronium Bromide and Neostigmine Metilsulfate.
Each glass ampoule contains 1ml 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 Bromide and Neostigmine Metilsulfate Injection looks like and contents of the pack

Glycopyrronium Bromide and Neostigmine Metilsulfate Injection is a clear, colourless, sterile solution for injection.
Each carton contains ten 1ml ampoules of Glycopyrronium Bromide and Neostigmine Metilsulfate 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

This leaflet was last revised in August 2019.