MercuryPharma

Package leaflet: Information for the user

Glycopyrronium Bromide 200micrograms/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, 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).

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. Its purpose is to dry up the secretions in your mouth and airways and to reduce the acidity of your stomach before an operation. It is also used to block some of the unwanted effects that may occur during an operation or from other medicines that may be used, such as slowing the heart rate or excess production of saliva.

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 of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Glycopyrronium Injection:
- if you are suffering from heart disease, heart failure, irregular heart beats or high blood pressure
- if you have an overactive thyroid gland
- if you have a high temperature (fever)
- if you have been administered inhalation anesthesia
- if you suffer from glaucoma (increased pressure in the eye)
- if you suffer from myasthenia gravis(leading to muscle weakness and fatiguability)
- 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 are pregnant or are breast feeding (see section Pregnancy and breast-feeding and fertility below).

Other medicines and Glycopyrronium Injection

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. A number of drugs can interact with Glycopyrronium Injection which can significantly alter their effects. These drugs include:
- Drugs for depression known as Tricyclic Antidepressants and Monoamine Oxidase Inhibitors (MAOIs)
- Clozapine which is used to treat severe mental disorders
- Strong pain relievers such as Nefopam
- Amantadine which is used to treat Parkinson's disease or viral infection.

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 or pharmacist for advice before using this medicine.

Driving and using machines

You should not drive or use machines after being given this medicine until the doctor advises you that you are safe to do so.

Glycopyrronium Injection contains sodium

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

3. HOW TO USE GLYCOPYRRONIUM INJECTION

Glycopyrronium Injection should be administered by a qualified healthcare professional.

continued overleaf

Method of administration:
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.

If you use more Glycopyrronium Injection than you should
This is unlikely because the dose will be administered by a health professional.
If you have any further questions on the use of this medicine ask your doctor, pharmacist 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.

Other side effects have also been reported under the following frequency

Very rare (may affect up to 1 in 10,000 people)
glaucoma (increased pressure in the eyes).

Not known (frequency cannot be estimated from the available data)

- a dry mouth
- blurred vision or reduced ability to sweat
- palpitations (an awareness of strong, thumping heart beats)
- fear of bright light
- confusion
- vomiting
- difficulty in passing water (urinating)
- a faster heart rate than normal
- difficulty in passing stools (constipation)
- reduced lung secretion
- redness and dryness of the skin
- feeling unwell
- feeling giddy.

If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor.

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: 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 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.
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.
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.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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