Glycopyrronium Injection may be used to:

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

Glycopyrronium bromide belongs to a group of medicines called anticholinergic drugs.

6. Contents of the pack and other information

5. How to store Glycopyrronium Injection

4. Possible side effects

3. How to use Glycopyrronium Injection

2. What you need to know before you use Glycopyrronium Injection

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

What is in this leaflet

This product will be referred to as Glycopyrronium Injection from here on.

Contains important information for you.

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 refer to 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 will be referred to as Glycopyrronium Injection from here on.

Warnings and precautions

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

• Drugs for depression known as Tricyclic Antidepressants (for example amitriptyline or imipramine) and Monoamine Oxidase Inhibitors (MAOIs) (for example phenelzine, tranylcypromine).

• Chlorpromazine which is used to treat severe mental disorders.

• Doxepin (used to treat mental disorders).

• Disulfiram (used to treat alcoholism).

• Benzodiazepines (such as lorazepam, diazepam, clonazepam).

• 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).

• Pethidine (used to treat moderate to severe pain).

• Quinidine (used to treat heart rhythm disorders).

• Minocycline (used to treat bacterial infections).

• Benzphetamine, ephedrine, pseudoephedrine (used to treat asthma, hay fever, and the common cold).

• Phenobarbital (used to treat slow heart rate).

• Metoclopramide (used to treat nausea and vomiting).

• Ketorolac (used to treat pain and inflammation).

• Naproxen (used to treat arthritis).

• Corticosteroids used to treat various conditions including asthma and inflammatory disease (for example prednisolone).

• Slow-dissolving digoxin tablets, disopyramide (used to treat heart problems).

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The recommended dose is:

**Dosage when used before an operation**

**Adults and elderly**

A single dose (0.2 to 0.4mg) may be injected into a vein or into a muscle before the anaesthetic is given. Alternatively, a dose of 4 to 5 micrograms per kilogram of body weight (0.004 to 0.006mg per kg) may be used, up to a maximum dose of 400 micrograms (0.4mg).

**Use in children and adolescents:**

A single dose of 0.2 micrograms (0.2 to 0.4mg) should be given by injection into a vein. Alternatively, a single dose of 4 to 5 micrograms per kilogram of body weight (0.004 to 0.006mg per kg) may be used, up to a maximum of 400 micrograms (0.4mg).

**Dosage when used during an operation**

**Adults and elderly**

A single dose of 0.2 micrograms (0.2 to 0.4mg) may be injected into a vein. Alternatively, a single dose of 4 to 5 micrograms per kilogram of body weight (0.004 to 0.006mg per kg) may be used, up to a maximum of 400 micrograms (0.4mg).

**Use in children and adolescents:**

A single dose of 0.15 micrograms (0.15 to 0.3mg) may be given by injection into a vein. Alternatively, a single dose of 4 to 5 micrograms per kilogram of body weight (0.004 to 0.006mg per kg) may be used, up to a maximum of 400 micrograms (0.4mg).

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

**Adults and elderly**

Dosage when reversing the effects of non-depolarising muscle relaxants is described in** 4.2.2.2.**

**Use in children and adolescents:**

10 micrograms per kilogram of body weight (0.01mg per kg) may be injected into a vein with 50 micrograms per kilogram (0.05mg per kg) of neostigmine or the equivalent dose of pyridostigmine. Glycopyrrolate injection may be administered at the same time and from the same syringe with the neostigmine or pyridostigmine.

**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 or nurse.

**HOW TO STORE GLYCOPHYRRONIUM INJECTION**

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.

- Severe symptoms, including:
  - 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 (swelling not known, cannot be estimated from the available data).
  - Other side effects have also been reported under the following frequency:
    - Very rare (may affect up to 1 in 10,000 people)
    - Rare (may affect up to 1 in 1,000 people)
    - Unlikely (may affect up to 1 in 100 people)
    - Very unlikely (may affect up to 1 in 10,000 people)

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

If you get 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 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.