3. How Glycopyrronium Injection is given to you
The recommended dose is:
Dosage when used before an operation
Adults and elderly
200 to 400 micrograms (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 0.005mg per kg) may be used, up to a maximum dose of 400 micrograms (0.4mg).
Use in children and adolescents:
4 to 8 micrograms per kilogram of body weight (0.004 to 0.008mg per kg) up to a maximum of 200 micrograms (0.2mg) may be injected into a vein or into a muscle before the anaesthetic is given.
Dosage when used during an operation
Adults and elderly
A single dose of 200 to 400 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 0.005mg per kg) may be used, up to a maximum of 400 micrograms (0.4mg). This dose may be repeated if necessary.
Use in children and adolescents
A single dose of 200 micrograms (0.2mg) should be given by injection into a vein. Alternatively, a single dose of 4 to 8 micrograms per kilogram of body weight (0.004 to 0.008mg per kg) may be used, up to a maximum of 200 micrograms (0.2mg). This dose may be repeated if necessary.
Dosage when reversing the effects of non-depolarising muscle relaxants
Adults and elderly:
200 micrograms (0.2mg) per 1,000 micrograms (1mg) of neostigmine or the equivalent dose of pyridostigmine, by injection into a vein.
Alternatively, a dose of 10 to 15 micrograms per kilogram of body weight (0.01 to 0.015mg per kg) may be injected into a vein with 50 micrograms per kg (0.05mg per kg) of neostigmine or equivalent dose of pyridostigmine. Glycopyrrolate Injection may be administered at the same time and from the same syringe with the neostigmine or pyridostigmine.
Use in children and adolescents
10 micrograms per kg of body weight (0.0lmg per kg) may be injected into a vein with 50 micrograms per kg (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 have been given 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.
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 • difficulty in passing water (urinating)
• blurred vision or reduced ability to sweat • a faster heart rate than normal
• palpitations (an awareness of strong, • difficulty in passing stools (constipation)
thumping heartbeats) • reduced lung secretion
• fear of bright light • redness and dryness of the skin
• confusion • feeling unwell
• vomiting • feeling giddy
• feeling sick (nausea) • unable to completely empty the bladder
• urgent need to urinate. (urinary retention)
• slow heart rate followed by rapid heart rate,
palpitations and irregular heartbeat
If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor.
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.
If only part used, discard the remaining solution.
Do not use this medicine if you notice the ampoule is damaged or if the contents are discoloured.
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
Glycopyrronium Injection is a clear, colourless, sterile solution for injection.
Each carton contains ten 1ml ampoules, of Glycopyrronium Injection in a Inner carton & 10 Inner in one Outer pack

Storage : Store in a dry place below 25°C. Protect from light & moisture. Do not freeze.
Improper storage may deteriorate the product.

Manufactured by:
AMERICAN REMEDIES © Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
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For the use only of a registered medical practitioner or a hospital or a laboratory

℞ Glycopyrrolate Injection I.P.

AMERICAN
GLYCOLYTE
Injection

FOR I.M./I.V. USE ONLY

Composition :
Each ml contains :

Glycopyrrolate	I.P.	0.2 mg
Water for Injection	I.P.	q.s.

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 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 are given Glycopyrronium Injection
3. How Glycopyrronium Injection is given to you
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 belongs to a group of medicines called anticholinergic drugs.
Glycopyrrolate Injection may be used
• to protect against some of the unwanted effects of drugs such as neostigmine or pyridostigmine, which are used to reverse the effects of certain types of muscle- relaxing drugs (called non-depolarising muscle relaxants)
• before an operation, to reduce saliva and other secretions and to make the stomach contents less acid
• before or during an operation, to reduce or prevent slowness of the heartbeat
2. What you need to know before you are given Glycopyrronium Injection
You must not be given Glycopyrronium Injection
• if you are allergic to glycopyrronium or any of the other ingredients of this medicine
• if you have glaucoma (increased pressure in the eye).
• if you suffer from myasthenia gravis (a disorder that causes extreme muscle weakness and fatigue).
• if you have an enlarged prostate.
• if you have stomach or bowel problems such as obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus).
. • if you are taking 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 Injection
• if you have Down's Syndrome.
• if you are over 60 years of age.
• if you are a child.
• if you have history of heart disease, heart attack, coronary heart disease or irregular heartbeats or high blood pressure.
• if you have a condition characterised by rapid heartbeat (including over-active thyroid, heart failure or heart surgery).
• if you have gastric reflux (a condition in which the liquid stomach contents backs up (regurgitates) into the gullet.
• if you have diarrhea
• if you have ulcerative colitis (an inflammation of the large intestine).
• if you have kidney disease you need to avoid repeated or large doses.
• if you have an overactive thyroid gland.
• if you have a high temperature (fever) (as the drug will inhibit sweating).
• if you have been administered inhalation anesthesia (to put you asleep before an operation) as it may cause a change in your normal heart rhythm.
• if you are pregnant or are breast feeding (see section Pregnancy and breast-feeding below).
Other medicines and Glycopyrronium Injection
Tell your doctor or nurse 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 (for example amitriptyline or imipramine) and Monoamine Oxidase Inhibitors (MAOIs) (for example phenelzine, tranylcypramine).
• Clozapine which is used to treat severe mental disorders.
• Strong pain relievers such as Nefopam
• Amantadine, levodopa which is used to treat Parkinson's disease or viral infection.
• 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).
• Domperidone or metoclopramide (used to treat nausea and vomiting).
• Ketoconazole (used to treat fungal infections).
• Memantine (used to treat Alzheimer's disease).
• Parasympathomimetics (these are drugs that affect chemicals in the body which are involved in transmission of nerve impulses to a muscle) (for example carbachol, neostigmine, physostigmine).
• Ritodrine (used to prevent uncomplicated premature labour).
• Corticosteroids used to treat various conditions including asthma and inflammatory disease (for example prednisolone).
• Slow-dissolving digoxin tablets, disopyramide (used to treat heart problems).
Glyceryl trinitrate tablets (used to treat angina) may not dissolve under the tongue as well as usual owing to the dry mouth which glycopyrronium causes.
Pregnancy and breast-feeding
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before you are given this medicine.
Driving and using machines
Glycopyrrolate may cause your eyesight to become blurred and this could interfere with your ability to drive or operate machinery safely. You should not drive or use machines after being given this medicine until the doctor advises you that you are safe to do so.