

APPROVED PATIENT INFORMATION LEAFLET

Scheduling status

S2

Proprietary name and dosage form

Fresenius Glycopyrrolate Injection 0,2 mg/1 ml

Fresenius Glycopyrrolate Injection 0,4 mg/2 ml

Injection

Read all of this leaflet carefully before you are given Fresenius Glycopyrrolate Injection:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Fresenius Glycopyrrolate Injection has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT FRESENIUS GLYCOPYRROLATE INJECTION CONTAINS

The active substance is glycopyrrolate 0,2 mg per 1 ml.

The inactive substances are: Sodium hydroxide, hydrochloric acid, nitrogen and water for injection.

WHAT FRESENIUS GLYCOPYRROLATE INJECTION IS USED FOR

Fresenius Glycopyrrolate Injection is used during surgery to decrease secretions such as saliva and during anaesthesia to keep the heart rate normal.

BEFORE YOU ARE ADMINISTERED FRESENIUS GLYCOPYRROLATE INJECTION

Fresenius Glycopyrrolate Injection should not be administered to you:

- if you are hypersensitive to glycopyrrolate or to any of the ingredients of Fresenius Glycopyrrolate Injection
- if you have an enlarged prostate
- if you have intestinal blockage

Special care should be taken with Fresenius Glycopyrrolate Injection:

- if you have glaucoma (increased pressure in the eye) or asthma
- in children and elderly patients
- if you have ulcerative colitis (an inflammatory disease affecting the lining of the colon and rectum) or diarrhoea
- if you have myasthenia gravis (a neuromuscular disorder manifested as ptosis (drooping eyelids), diplopia (double vision), weakness in arms, hands, fingers, legs and neck, change in facial expression, dysphagia (difficulty swallowing), shortness of breath and dysarthria (impaired speech))
- if you have fever
- if you have a high heart rate, high blood pressure and other serious heart conditions.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving Fresenius Glycopyrrolate Injection.

You should not receive Fresenius Glycopyrrolate Injection if you are pregnant or breastfeeding your baby. The safety of Fresenius Glycopyrrolate Injection has not been established.

Driving and using machinery:

Fresenius Glycopyrrolate Injection can cause blurred vision and dizziness. You are advised not to drive or operate machinery, if you experience these side effects.

Using other medicines with Fresenius Glycopyrrolate Injection:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Inform your doctor if you are taking any of the following medicines:

- amantadine (antiviral medicine for certain influenza infections)
- antihistamines (medicine used to treat allergies and inflammatory conditions)
- phenothiazine type antipsychotic medicines
- tricyclic type antidepressant medicines

HOW FRESENIUS GLYCOPYRROLATE INJECTION WILL BE ADMINISTERED

You will not be expected to give yourself Fresenius Glycopyrrolate Injection. It will be given to you by a person who is qualified to do so.

The dosage, method and route of administration, frequency of administration and duration of treatment will be decided by the doctor or healthcare professional based on your condition.

If you are given more Fresenius Glycopyrrolate Injection than you should:

Since a healthcare professional will administer Fresenius Glycopyrrolate Injection, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

In the case of overdose, you may experience increased side effects such as high body temperature, high blood pressure, increased respiration, nausea and vomiting and a rash on the face and upper body. Your doctor may give you appropriate treatment for these side effects.

If you have any questions about your treatment, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Fresenius Glycopyrrolate Injection can have side effects.

Not all side effects reported for Fresenius Glycopyrrolate Injection are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Fresenius Glycopyrrolate Injection, please consult your doctor, pharmacist or other healthcare professional for advice.

Check with your doctor immediately if any of the following side effects occur:

- dry mouth with difficulty swallowing and talking
- thirst
- decreased bronchial secretions
- dilation of pupils
- difficulty in vision
- sensitivity to light
- redness and dryness of the skin
- slow heart rate followed by a rapid heart rate
- heart beat abnormalities
- difficulty in passing urine
- constipation

Other side effects include:

- headache
- nervousness
- drowsiness
- weakness
- dizziness

- difficulty in falling asleep
- mental confusion
- nausea and vomiting
- difficulty in maintaining an erection
- difficulty in breastfeeding

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF FRESENIUS GLYCOPYRROLATE INJECTION

Store all medicines out of reach of children.

Store at or below 25 °C.

PRESENTATION OF FRESENIUS GLYCOPYRROLATE INJECTION

1 ml or 2 ml clear glass ampoules in boxes of 10.

IDENTIFICATION OF FRESENIUS GLYCOPYRROLATE INJECTION

A clear, colourless solution in 1 ml or 2 ml clear glass ampoules.

REGISTRATION NUMBER

Fresenius Glycopyrrolate Injection 0,2 mg/1 ml: A40/5.4/0101

Fresenius Glycopyrrolate Injection 0,4 mg/2 ml: A40/5.4/0044

NAME AND ADDRESS OF REGISTRATION HOLDER

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