

Hospira™ Glycopyrrolate Injection

Glycopyrronium bromide (glycopyrrolate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hospira™ Glycopyrrolate Injection. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Hospira™ Glycopyrrolate Injection against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Hospira™ Glycopyrrolate Injection is used for

Hospira™ Glycopyrrolate Injection may be used;

- before surgery to reduce the amount of saliva produced by your mouth, and other secretions produced in your lungs and stomach
- before or during surgery to maintain your heart's normal beating rhythm, or
- it may also be used to counter the effects of some other medicines, which can slow your heartbeat or produce excessive secretions when used during surgery.

This medicine belongs to a group of medicines called "anticholinergics" which work in the nervous system to block an enzyme which is responsible for producing saliva in your mouth, and secretions in your stomach and lungs. This enzyme also slows down the heart rate. When this enzyme is blocked, secretions dry up and the heart rate increases.

Your doctor may have prescribed Hospira™ Glycopyrrolate Injection for another purpose.

Ask your doctor if you have any questions about why Hospira™ Glycopyrrolate Injection has been prescribed for you.

Hospira™ Glycopyrrolate Injection is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Hospira™ Glycopyrrolate Injection

When you must not be given it

Do not have Hospira™ Glycopyrrolate Injection if you are allergic to Hospira™ Glycopyrrolate Injection or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not have Hospira™ Glycopyrrolate Injection if the packaging is torn or shows signs of tampering.

Do not have Hospira™ Glycopyrrolate Injection after the expiry date (EXP) printed on the pack.

If you have it after the expiry date has passed, it may not work as well. The

pharmacist will check that the medicine is suitable for use before you are given it.

Before you are given it

Tell your doctor if you have any allergies to any other medicines, any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to breastfeed. Your doctor will discuss the risks and benefits of receiving Hospira™ Glycopyrrolate Injection during pregnancy. It may also reduce your milk supply. It is not known if Hospira™ Glycopyrrolate Injection is found in breast milk.

Tell your doctor if you have, or have had, any other medical conditions including:

- asthma
- glaucoma, (increased pressure in your eyes)
- diarrhea or constipation
- stomach or bowel problems
- hiatus hernia
- heart disease or high blood pressure
- hyperthyroidism
- fever
- myasthenia gravis (muscle weakness)
- kidney problems or difficulty urinating
- nerve or brain disorder, brain damage
- Down's Syndrome.

If you have not told your doctor about any of the above, tell them before you are given Hospira™ Glycopyrrolate Injection.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Hospira™ Glycopyrrolate Injection. These include:

- ritodrine hydrochloride
- belladonna alkaloids
- medicines for Parkinson's disease
- antidepressants
- phenothiazines, (used to treat mental illness or severe nausea and vomiting)
- disopyramide
- procainamide
- quinidine
- antihistamines
- narcotic pain killers (pethidine, thioxanthenes, butyrophenones or amantadine)
- digoxin (used to treat heart failure)
- any corticosteroids
- medicines used to control heart rhythm
- any other anticholinergic medicines.

These medicines may be affected by Hospira™ Glycopyrrolate Injection or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with,

or avoid, when given Hospira™ Glycopyrrolate Injection.

How Hospira™ Glycopyrrolate Injection is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much is given

The dose of Hospira™ Glycopyrrolate Injection may be different for each person. The dose given will depend on your condition, age and body weight. The usual adult dose is 200 to 400 micrograms. Your doctor will decide the right dose for you. For children aged 1 month to 12 years, the usual dose depends on their bodyweight.

How it is given

Hospira™ Glycopyrrolate Injection will be given to you by injection into either a vein or a muscle before the anaesthetic.

How long is it given for

Hospira™ Glycopyrrolate Injection is usually given as a single dose. However, sometimes your doctor may decide you need more. Your doctor will decide how much Hospira™ Glycopyrrolate Injection you need.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Hospira™ Glycopyrrolate Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are having Hospira™ Glycopyrrolate Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Hospira™ Glycopyrrolate Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

Always discuss with your doctor any problems or difficulties during or after having Hospira™ Glycopyrrolate Injection.

Things you must not do

Do not drive or operate machinery, or perform hazardous work until you know how Hospira™ Glycopyrrolate Injection affects you.

Hospira™ Glycopyrrolate Injection may cause drowsiness or blurred vision in some people and therefore may affect alertness.

Things to be careful of

Be careful if you are elderly, unwell or taking other medicines.

You may experience side effects such as drowsiness or blurred vision, which may increase the risk of a fall.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful during warm weather and higher temperature, and/or with physical exercise after use of Hospira™ Glycopyrrolate Injection.

It may reduce your ability to sweat and can therefore cause overheating.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having Hospira™ Glycopyrrolate Injection.

Hospira™ Glycopyrrolate Injection may have unwanted side effects in some people.

All medicines may have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- fast, slow or irregular heart beats
- flushing skin, or inability to sweat
- dry and/or itchy skin
- feeling sick or vomiting
- Nausea, vomiting
- dry mouth, constipation
- taste alterations, or loss of taste
- difficulty urinating
- impotence
- blurred vision, other problems with eyes
- dizziness
- seizures
- insomnia (inability to sleep)
- headache, nervousness, drowsiness
- mental confusion in elderly
- over-excitement in children
- reduced milk supply in breastfeeding women
- headache
- nervousness, drowsiness
- fever or feeling hot
- bloated feeling
- muscular weakness or possibly paralysis
- injection site reactions like itchy skin, swelling, pain.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- cold sweat, nausea, light headedness, discomfort in chest or other areas of the upper body like pain or discomfort in

one or both arms, the back, neck, jaw or stomach

- muscular weakness or possibly paralysis.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After having Hospira™ Glycopyrrolate Injection

Storage

Hospira™ Glycopyrrolate Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, stored below 25°C.

Disposal

The hospital staff will dispose of any leftover product.

Product description

What it looks like

Hospira™ Glycopyrrolate Injection comes as a clear, colourless solution in a clear glass ampoule.

Ingredients

Each ampoule of Hospira™ Glycopyrrolate Injection contains glycopyrronium bromide (glycopyrrolate) as the active ingredient.

Each 1 mL ampoule contains 200 micrograms of glycopyrronium bromide (glycopyrrolate). It also contains:

- Water for Injections
- Sodium Chloride and
- Hydrochloric acid

Hospira™ Glycopyrrolate Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Hospira™ Glycopyrrolate Injection is supplied by:

Australia:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
WEST RYDE NSW 2114

Toll Free Number:
1800 675 229

Hospira™ Glycopyrrolate Injection is available in the following strengths:

- 200 micrograms/mL
AUST R 220016

This leaflet was prepared March 2017.