

ROBINUL® Injection

glycopyrrolate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ROBINUL 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 ROBINUL 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 ROBINUL Injection is used for

ROBINUL is used before surgery to decrease the volume of secretions from your mouth, lungs and stomach.

It can also be used either before or during surgery to maintain your heart's normal beating rhythm.

ROBINUL is also used to counter the effects of some other medicines, which can slow your heartbeat or produce excessive secretions when used during surgery

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

Your doctor, however, may have prescribed it for another purpose.

ROBINUL works in the nervous system by blocking 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.

ROBINUL Injection is not habit forming.

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

Before you are given it

When you must not be given it

Do not have ROBINUL Injection if:

- You are allergic to ROBINUL 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.
- You are breastfeeding or plan to breastfeed.**

Medicines like ROBINUL may reduce your milk supply. It is not known if ROBINUL is found in breast milk.

Do not have ROBINUL Injection if the packaging is torn or shows signs of tampering.

Do not have ROBINUL 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.

Before you are given it

You must tell your doctor if:

- You have any allergies to:**

- any other medicines
 - any other substances, such as foods, preservatives or dyes
 - latex rubber.
- You are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of receiving ROBINUL during pregnancy.
 - You have or have had any other medical conditions including:**
 - asthma
 - glaucoma, which is an increased pressure in your eyes
 - diarrhoea
 - problems with your heart, kidney or thyroid
 - difficulty urinating, or enlarged prostate
 - stomach or bowel problems
 - hiatus hernia that causes heartburn and belching
 - high blood pressure
 - myasthenia gravis, a muscle weakness disorder
 - nerve or brain disorder, brain damage, or Down's Syndrome.

If you have not told your doctor about any of the above, tell them before you are given ROBINUL 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 ROBINUL. These include:

- ritodrine hydrochloride
- medicines for Parkinson's disease
- phenothiazines, which are used to treat mental illness or severe nausea and vomiting
- antidepressants
- antihistamines
- narcotic pain killers such as pethidine
- medicines used to control heart rhythm
- digoxin used to treat heart failure
- thioxanthenes
- butyrophenones
- amantadine.

These medicines may be affected by ROBINUL or may effect 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 ROBINUL Injection.

How ROBINUL Injection is given

How much is given

A doctor gives ROBINUL Injection to you. The dose of ROBINUL may be different for each person. The dose given depends on your condition, age, body weight and your doctor. Your doctor will decide the right dose for you. For children aged 1 month to 12 years, the usual dose depends on their body weight.

When used before surgery the usual adult dose is 0.2 to 0.4mg given by injection into either a vein or a muscle. You will get ROBINUL before the anaesthetic is given.

For use during surgery, the usual adult dose is a single injection of 0.2 to 0.4mg into a vein. Sometimes the dose may need to be repeated. Your doctor will decide if this needs to happen.

To counter the effects of other medicines, the usual adult dose of ROBINUL is 0.2mg per 1mg neostigmine or the equivalent dose of pyridostigmine given by injection into a vein.

How it is given

A doctor gives ROBINUL Injection to you. The injection is usually given into a muscle or a vein.

If ROBINUL is given to counter the effects of other medicines, it may be given in the same syringe as the neostigmine or pyridostigmine.

How long is it given

ROBINUL injection is usually given as a single dose, but sometimes a dose must be repeated. Your doctor will decide how many doses of ROBINUL Injection are needed.

While you are having it

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you have had ROBINUL Injection.

Tell your doctor if you feel ROBINUL is not helping your condition.

Always discuss with your doctor any problems or difficulties during or after having ROBINUL Injection.

Things you must not do

Do not drive or operate machinery until you know how ROBINUL Injection affects you.

ROBINUL may cause drowsiness or dizziness or blurred vision in some people and therefore may affect alertness.

Make sure you know how you react to ROBINUL injection before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Things to be careful of

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

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

Be careful during warm weather and temperature, and/or with physical exercise after use of ROBINUL.

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 ROBINUL Injection.

ROBINUL helps most people with your condition, but it 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
- unable to sweat
- feeling sick or vomiting
- dry mouth
- dry and/or itchy skin
- constipation
- difficulty urinating
- impotence
- reduced milk supply in breastfeeding women
- blurred vision or other problems with your eyesight
- headache
- nervousness, drowsiness
- dizziness
- unable to sleep
- over-excitement in children
- confusion, especially in elderly people
- fever
- feeling bloated
- loss or alteration of taste.

These side effects are usually mild.

Rare side effects include: injection site reactions like itchy skin, swelling, pain

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

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

Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking, ROBINUL Injection.

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

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 it

Storage

ROBINUL Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

ROBINUL Injection comes in a clear glass 1 mL ampoule containing a clear, colourless solution. Available in packs of 5 single dose ampoules.

Ingredients

The active ingredient in ROBINUL Injection is glycopyrrolate. Each 1 mL ampoule contains 0.2 mg/mL of glycopyrrolate.

Excipients include water for injections, sodium chloride and sodium hydroxide/hydrochloride acid (for pH adjustment).

It does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

Australian Registration Number

1 mL ampoule: AUST R 163586

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