

Midazolam Injection

Midazolam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Midazolam Injection.

It does not contain all 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 Midazolam injection against the benefits it is expected to have for you.

This medicine is likely to be used while you are in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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

Keep this leaflet.

You may need to read it again.

What Midazolam Injection is used for

What it does

Midazolam is used as a sedative during short medical procedures, before you have an operation or if you are in intensive care. Midazolam may also be given to help induce anaesthesia before you are given another anaesthetic.

It belongs to a group of medicines called benzodiazepines.

How it works

This medicine works by slowing down the brain to cause sleepiness and temporary loss of memory and anaesthesia to prevent pain and discomfort during surgery.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Before you are given Midazolam Injection

When you must not be given it

You will not be given Midazolam Injection if you have an allergy to:

- any medicine containing midazolam or any other benzodiazepines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use Midazolam Injection if you have or have had any of the following medical conditions:

- myasthenia gravis
- acute narrow angle glaucoma.

You will not be given this medicine if you are suffering from shock,

coma or acute alcoholic intoxication.

This medicine should not be given to a child under the age of 8 years.

Safety and effectiveness in children younger than 8 years have not been established.

Midazolam Injection should not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

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

Tell your doctor if you have or have had any of the following medical conditions:

- kidney, liver or heart problems
- breathing problems such as asthma, bronchitis, emphysema, or chronic obstructive pulmonary disease
- epilepsy
- history of drug or alcohol abuse.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Midazolam Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Midazolam injection or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat depression
- sleeping tablets or medicines to treat anxiety
- pain relievers including opioids
- medicines used to control epilepsy, such as carbamazepine, phenytoin
- antihistamines, a type of medicine used for allergies and colds
- antibiotics such as rifampicin, erythromycin
- antifungal agents such as ketoconazole, fluconazole, itraconazole
- antivirals such as ritonavir and saquinavir
- cimetidine, a medicine used to treat stomach
- atorvastatin, a medicine used to lower cholesterol
- medicines used to treat heart problems such as diltiazem, verapamil
- echinacea, a herb used to prevent and treat colds and flu
- alcohol
- St John's Wort, a herb used to treat depression.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Midazolam Injection is given

Midazolam Injection must only be given by a doctor or nurse.

It may be given as an injection into a vein or muscle, or through an intravenous infusion.

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your age, how well your kidneys and liver are working, and whether or not other medicines are being given at the same time.

How long it is given for

Midazolam Injection is given as a single dose before a medical procedure, or continuously by infusion. It is stopped once there is no further need for sedation.

If you are given too much (overdose)

This rarely happens as Midazolam Injection is administered under the care of a highly trained doctor or nurse. Your condition will be carefully monitored following administration.

However, if you are given too much midazolam, you may feel drowsy, tired, confused, dizzy, weak or become unconscious.

Whenever you are given Midazolam Injection, equipment is available to treat you if you experience severe side effects.

If you think you have been given too much Midazolam Injection or if you experience severe side effects, tell your doctor or nurse immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have been given Midazolam Injection.

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

All medical procedures which involve the use of an anaesthetic have a very small risk which your doctor will discuss with you.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the list of side effects.

You may not experience any of them.

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

Tell your doctor if...

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

- pain, redness or hardness at the site of injection
- muscle stiffness or inflammation
- nausea, vomiting
- headache
- drowsiness, tiredness
- dizziness, unsteadiness
- hiccups
- coughing.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- difficulty breathing
- chest pain
- confusion, hallucinations
- sudden anxiety, aggression or hostility.

The above list includes very serious side effects. You may need urgent

medical attention. These side effects are rare.

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

Other side effects not listed above may also occur in some people.

Some of these side effects, for example, changes in blood pressure or pulse rate will be monitored by your nurse from time to time to check your progress until you leave hospital.

After using Midazolam Injection

Be careful driving or operating heavy machinery after you have been given Midazolam Injection.

After having Midazolam Injection, you may be drowsy or not fully alert. Your ability to drive a car or to operate machinery may be affected for some time. You should arrange to be accompanied home by a responsible adult.

Ask your doctor when you can return to activities such as driving a vehicle or operating machinery.

Do not drink alcohol for at least 12 hours after receiving Midazolam Injection.

Alcohol can increase the risk of side effects including difficulty breathing and prolonged sedation.

Storage

This medicine should be stored in the hospital pharmacy or on the ward, in a cool dry place below 25°C and protected from light.

Disposal

Any Midazolam Injection which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Midazolam Injection is for single use only.

Product description

What it looks like

Midazolam Injection is a clear, colourless to pale yellow solution in a 1mL, 5mL or 10mL plastic ampoule.

Ingredients

Midazolam Injection contains 1 mg/mL or 5 mg/mL of midazolam (as the hydrochloride) as the active ingredient.

It also contains:

- sodium chloride
- sodium hydroxide
- hydrochloric acid
- Water for Injections.

This medicine does not contain a preservative.

Supplier

Midazolam Injection is supplied by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizer.com.au .

Australian registration numbers

5mg in 1mL: Steriluer® Plastic Ampoule (2 x 5 pack) AUST R 72213

5mg in 5mL: Steriluer® Plastic Ampoule (2 x 5 pack) AUST R 72214

50mg in 10mL: Steriluer® Plastic Ampoule (5 pack) AUST R 72207

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Steriluer® is a plastic ampoule produced by Pfizer.

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