

Midazolam Sandoz®

midazolam injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Midazolam Sandoz. It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Midazolam Sandoz against the benefits they expect it will have for you.

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

Keep this leaflet after your operation or hospital stay.

You may need to read it again.

What Midazolam Sandoz is used for

Midazolam Sandoz belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

Midazolam Sandoz may be injected as a sedative during some short medical procedures.

Midazolam Sandoz may be given to you by injection before an operation to produce sleepiness or drowsiness.

If you are in an intensive care unit, you may receive an infusion of Midazolam Sandoz over several hours or days as a sedative.

However, your anaesthetist or surgeon may have prescribed Midazolam Sandoz for another reason.

Ask your doctor if you have any questions about why Midazolam Sandoz has been prescribed for you.

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

Before you are given Midazolam Sandoz

When you must not use it

Do not use Midazolam Sandoz if

- you have an allergy to:**
 - midazolam, or any of the other ingredients listed at the end of this leaflet
 - any other medicine from the benzodiazepine group of medicines.Symptoms of an allergic reaction may include asthma, wheezing or shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash or fainting.
- you have severe muscle weakness, also known as myasthenia gravis.**
- you have acute narrow angle glaucoma (high pressure in the eye).**

Midazolam Sandoz should not be given to you if you are in shock, coma or in acute alcoholic intoxication.

If you are not sure whether you should be given Midazolam Sandoz, talk to your doctor.

Midazolam Sandoz should not be given to children younger than eight years of age.

The safety and effectiveness of Midazolam Sandoz in children less than eight years of age have not been established.

Before you are given it

Tell your doctor if:

- you are pregnant, or intend to become pregnant.**

Like most medicines, Midazolam Sandoz is not recommended for use during pregnancy. Your doctor will discuss the possible risks and benefits of using Midazolam Sandoz during pregnancy.
- you are breast-feeding or intend to breast-feed.**

Midazolam Sandoz passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. Midazolam Sandoz is not recommended for use while breast-feeding. Your doctor will discuss the risks and benefits of using Midazolam Sandoz when breast-feeding.
- you have or have had any other health problems including:**
 - breathing or lung problems
 - liver or kidney problems
 - epilepsy (fits or convulsions)
 - high or low blood pressure
 - mental disorders including depression, psychosis or schizophrenia
 - heart problems
 - history of alcohol or drug abuse.
- you drink alcohol regularly**

Alcohol should be avoided for at least 12 hours after receiving Midazolam Sandoz. Combining alcohol and Midazolam Sandoz may make you more sleepy, dizzy or lightheaded.
- you are allergic to any other medicines, foods, dyes or preservatives.**

If you have not told your doctor about any of the above, tell them before you use any Midazolam Sandoz.

Taking other medicines

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

Some medicines may interfere with Midazolam Sandoz. These include:

- sedatives, medicines used to calm you down or help you sleep
- pain relievers
- muscle relaxants
- medicines for depression
- medicines to control fits
- medicines for allergies or colds e.g. antihistamines or cold tablets
- cimetidine, a medicine used to treat ulcers
- disulfiram, a medicine used in alcohol abuse
- erythromycin and rifampicin, types of antibiotic
- medicines to treat heart problems or high blood pressure e.g. diltiazem, verapamil

- medicines to treat fungal infections e.g. ketoconazole, itraconazole, fluconazole
- other anaesthetics
- medicines for HIV/AIDS infection e.g. ritonavir, saquinavir.

These medicines may be affected by Midazolam Sandoz or may affect how well Midazolam Sandoz works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Midazolam Sandoz.

How Midazolam Sandoz is given

Midazolam Sandoz is given by an injection into a vein or muscle.

It may also be given through an infusion set in an intensive care unit. Other medicines may also be given at the same time.

Your anaesthetist will decide what dose and how long you will receive Midazolam Sandoz. The dose of Midazolam Sandoz will be adjusted to keep you at the right depth of sleep or sedation. Lower doses may be given to elderly patients.

Midazolam Sandoz may be given once before a medical procedure, or continuously by infusion for patients in an intensive care unit.

If you have been given too much (overdose)

As Midazolam Sandoz is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given Midazolam Sandoz, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

If you have received too much Midazolam Sandoz, you may feel drowsy, tired, confused, dizzy, weak or become unconscious.

While you are receiving Midazolam Sandoz

Your anaesthetist, surgeon and nursing staff are trained to look after every need that you have while you are asleep or sedated. If you are receiving Midazolam Sandoz for general anaesthesia, the anaesthetist may need to use several different medicines to keep you asleep, pain free, breathing in a healthy way and with good blood pressure.

If you are receiving Midazolam Sandoz for sedation, other drugs are given at the same time. The mix and doses of drugs needs to be chosen by specially trained doctors and adjusted for each patient according to their need.

Things you must do

Tell your doctor if you feel Midazolam Sandoz is not helping you.

Things you must not do

After receiving Midazolam Sandoz your ability to drive a car or to operate machinery may be affected for some time.

Therefore, if you are able to go home soon after your operation, do not drive a car or operate machinery. This is important. Ask your doctor when you can return to activities such as driving a vehicle or operating machinery.

Do not have any alcohol for at least 12 hours after you have been given Midazolam Sandoz.

Things to be careful of

Be careful if you are elderly as you may be at an increased risk for falls and fractures.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after you have received Midazolam Sandoz.

All medicines can 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. Some of the unwanted side effects of Midazolam Sandoz are the result of sleep being too light or too deep. Your anaesthetist will reduce the dose of Midazolam Sandoz if your blood pressure is low, or if you need help breathing. However, your anaesthetist may increase the dose if body movement is still observed. Other medicines may also be needed if your heart rate becomes too slow or irregular.

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

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

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams
- blurred vision
- pain, redness or hardness at the injection site
- muscle stiffness or inflammation of the vein
- headache, hiccups
- feeling sick with or without vomiting
- agitation
- tremor.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rash
- asthma, wheezing or shortness of breath
- change in pulse rate or blood pressure
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- sudden anxiety or excitation
- hallucinations or delusions
- severe sleep disturbances.

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

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

doctor if you notice anything that is making you feel unwell.

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

After using Midazolam Sandoz

Storage

Midazolam Sandoz will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 25°C. It should be protected from light.

Product Description

What it looks like

Midazolam Sandoz is a clear, colourless solution, which is supplied in an ampoule.

Midazolam Sandoz ampoules come in packs of 5's (5mg/5mL, 15mg/3mL, 50mg/10mL) or 10's (5mg/1mL).

Ampoules are intended for single patient use only. Any remaining content should be discarded.

Ingredients

Active ingredient:

- midazolam 1mg/mL or 5mg/mL

Inactive ingredients:

- sodium chloride
- hydrochloric acid
- sodium hydroxide
- water for injections.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 634 500

Australian Register Numbers

5mg/5mL - AUST R 78971
5mg/1mL - AUST R 78972
15mg/3mL - AUST R 78974
50mg/10mL - AUST R 78976

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