

MIDAZOLAM APOTEX Solution for Injection

Contains the active ingredient midazolam

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet for information on your medicine.

This leaflet answers some common questions about midazolam. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about being given this medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with you. You may want to read it again.

What this medicine is used for

The name of your medicine is MIDAZOLAM APOTEX solution for injection. It contains the active ingredient midazolam.

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

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

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

Midazolam belongs to a group of medicines called benzodiazepines. Midazolam can cause sedation, hypnosis, amnesia and/or anaesthesia, depending on the dose.

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

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

Midazolam is only given by a doctor trained to use this medicine. If you will be receiving midazolam during surgery, your doctor will give you the medicine and closely follow your progress.

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

How it works

Benzodiazepines are thought to work by their action on brain chemicals.

As with other benzodiazepines, midazolam may have the potential to cause dependence. Benzodiazepines should be avoided in patients with a history of alcohol or drug abuse. The risk of dependence increases with the duration of treatment; it is also greater in patients with a medical history of alcohol and/or drug abuse.

Use in children

This medicine should not be used in children.

Before you are given this medicine

When you must not be given it

You must not be given this medicine if:

- you have had an allergic reaction to midazolam, any other benzodiazepine medicine, or any of the ingredients listed at the end of this leaflet
- you have severe muscle weakness, also known as myasthenia gravis
- you have a condition called acute narrow angle glaucoma
- you are suffering from shock, coma or acute alcoholic intoxication
- you are hypersensitive to, or have had an allergic reaction to, midazolam or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, tell your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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

Midazolam should not be given to children.

The safety or effectiveness of midazolam in children less than eight years of age has not been established.

Before you are given it

Before you are given this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver, kidney, heart or lung disease
 - high or low blood pressure
 - mental disorders including: depression, psychosis or schizophrenia
 - epilepsy (fits or convulsions)
 - history of alcohol or drug abuse
3. If you are pregnant or plan to become pregnant.

It is not known whether midazolam is harmful to an unborn baby when given to a pregnant woman. If there is a need to use midazolam when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.
4. If you are breastfeeding or plan to breastfeed. Midazolam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Midazolam is not recommended for use while breastfeeding.
5. If you drink alcohol regularly.

Be careful when drinking alcohol before receiving midazolam. Combining midazolam

and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest that you avoid alcohol for at least 12 hours before you receive midazolam.

6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with midazolam. These include:

- other sleeping tablets, sedatives or tranquillisers
- anaesthetics
- medicines for depression
- medicines to control fits such as sodium valproate
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- cimetidine, a medicine used to treat ulcers
- disulfiram a medicine used in alcohol abuse
- erythromycin, a common antibiotic
- diltiazem and verapamil, medicines used to treat high blood pressure or heart conditions
- verapamil
- ketoconazole, fluconazole and itraconazole, medicines used to treat fungal infections
- ritonavir and saquinavir, medicines used to treat HIV.

If you have not told your doctor or nurse about any of the above, tell them before you receive midazolam.

If you are taking any of these you may need a different dose or you may need to be given a different medicines.

Other medicines not listed above may also interact with midazolam.

How this medicine is given

How much is given

Your doctor will adjust the dose necessary for you. This depends on which medical procedure you will be having, your age, weight and your general health. Elderly patients may need to receive less.

How it is given

Midazolam may be given to you as an injection into a vein or muscle. It may also be given through an infusion set in an intensive care unit. Other medications may also be given at the same time.

How long it is used for

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

Midazolam will be stopped once there is no further need for sedation.

If you have been given too much (overdose)

If you think that you or anyone else may have been given too much of this medicine, immediately tell a doctor or nurse, or go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are being given this medicine

Things you must do

Tell your doctor that you are about to be given this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Tell your doctor if you feel midazolam is not helping you.

Things you must not do

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

Midazolam may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to midazolam before you drive a car or operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

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

Things to be careful of

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

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Possible side effects

Tell your doctor as soon as possible if you do not feel well when you have been given midazolam or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

All medical procedures which involve the use of an anaesthetic have risks, which your doctor will discuss with you.

In elderly, or high risk patients, death has resulted rarely due to a slowdown of the heart and lungs.

Tell your doctor if you notice any of the following:

- 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
- coughing, hiccups
- feeling sick with or without vomiting

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

These may be serious side effects and you may need medical attention:

- difficulty breathing
- changes in pulse rate and blood pressure
- sudden anxiety or excitement
- hallucinations or delusions
- severe sleep disturbances

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

Allergic reactions

If you think you are having an allergic reaction to midazolam, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Midazolam will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 30°C. It should be protected from light.

Disposal

Midazolam solution for injection is used for one dose in one patient only. Any remaining contents should be discarded.

Product description

What MIDAZOLAM APOTEX solution for injection looks like

Clear colourless to pale yellow solution for injection.

Midazolam ampoules 5mg/5mL, 15mg/3mL, 50mg/10mL, come in a pack size of 5 ampoules.

Midazolam ampoules 5mg/1mL come in a pack size of 10 ampoules.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each ampoule contains 5mg/5mL and 5mg/1mL of midazolam as the active ingredient.

It also contains the following inactive ingredients:

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

Australian Registration Numbers

Midazolam-APOTEX 1mg/mL solution for injection ampoules:

5mL AUST R 217663.

Midazolam-APOTEX 5mg/5mL solution for injection ampoules:

1mL AUST R 217657

3mL AUST R 217658

10mL AUST R 217659.

Sponsor

Apotex Pty Ltd

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This leaflet was last updated in February 2015.