

# MIDAZOLAM APOTEX Solution for Injection

Midazolam

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## Consumer Medicine Information

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

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### What is in this leaflet

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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.

**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](http://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.

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### What this medicine is used for

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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.

#### *How it works*

Midazolam belongs to a group of medicines called benzodiazepines.

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

Midazolam can cause sedation, hypnosis, amnesia and/or anaesthesia, depending on the dose.

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.

**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.

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

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.

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### Before you are given this medicine

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#### *When you must not be given it*

**You must not be given this medicine if you have an allergy to:**

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

Some of the 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
- hay fever-like symptoms.

**Do not take this medicine if you have or have had any of the following medical conditions:**

- severe muscle weakness, also known as myasthenia gravis

- acute narrow angle glaucoma
- shock, coma or acute alcoholic intoxication

**Midazolam should not be given to children under the age of 8 years.**

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

**If you are not sure whether you should be given midazolam, 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 conditions:**

- 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

**Tell your doctor if you are pregnant or plan to become pregnant.**

Midazolam is not recommended for use in pregnant woman, especially in the third (last) trimester or during labour. 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.

**Tell your doctor 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.

**Tell your doctor if you drink alcohol or use illicit (illegal) drugs regularly.**

Midazolam can cause physical dependency, especially if you have a history of drug or alcohol abuse, when used long-term. Your dose may be reduced gradually to overcome this effect.

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.

*Taking other medicines*

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

Some medicines and midazolam may interfere with each other. These include:

- other sleeping tablets, sedatives or tranquilisers
- anaesthetics
- medicines for depression, such as fluvoxamine
- 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, rifampicin and clarithromycin, antibiotics used to treat bacterial infections
- diltiazem, verapamil and atorvastatin, medicines used to treat high blood pressure or heart conditions
- ketoconazole, fluconazole, posaconazole and itraconazole, medicines used to treat fungal infections
- certain medicines used to treat HIV, such as ritonavir, saquinavir and efavirenz
- bicalutamide, a medicine used in the treatment of prostate cancer and for excessive hair loss (particularly in women)

- aprepitant, a medicine used to treat nausea and vomiting associated with chemotherapy
- certain complementary medicines, including echinacea, St John's Wort and goldenseal

These medicines may be affected by this medicine 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with midazolam.

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## How this medicine is given

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*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)*

**Immediately tell a doctor or nurse or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much of this**

**medicine. 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.

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## While you are being given this medicine

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### *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 are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast feed

**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, dizziness, fatigue, confusion and forgetfulness 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.

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## Possible side effects

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**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well when you have been given midazolam.**

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 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.

**Do not be alarmed by the following lists 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, nurse or pharmacist 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
- constipation

The above list includes the more common side effects of your medicine.

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

- changes in pulse rate and blood pressure
- sudden anxiety or excitation
- hallucinations, mood changes or delusions
- severe sleep disturbances

The above list includes serious side effects that may need medical attention.

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

**If any of the following happen, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:**

- 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

The above list includes signs of an allergic reaction. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

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

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## Storage and disposal

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### *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.

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## Product description

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### *What MIDAZOLAM APOTEX solution for injection looks like*

Clear colourless to pale yellow solution for injection.

Midazolam ampoules 5 mg/5 mL, 15 mg/3 mL, 50 mg/10 mL, 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:  
5 mL AUST R 217663.

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

1 mL AUST R 217657.

3 mL AUST R 217658.

10 mL AUST R 217659.

### *Sponsor*

Apotex Pty Ltd  
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Macquarie Park NSW 2113

This leaflet was last updated in: July 2018.