

MIDAZOLAM INJECTION

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or nurse.

1. Why am I being given MIDAZOLAM INJECTION?

MIDAZOLAM INJECTION contains the active ingredient midazolam. It is used as a sedative during short medical procedures, or as part of an operation, or may be needed if you are in intensive care.

For more information, see Section [1. Why am I being given MIDAZOLAM INJECTION?](#) in the full CMI.

2. What should I know before being given MIDAZOLAM INJECTION?

Do not use if you have ever had an allergic reaction to midazolam or any other benzodiazepines or any of the ingredients listed at the end of the CMI, have myasthenia gravis, short angle glaucoma or immediate severe alcohol intoxication.

Talk to your doctor if you have any other medical conditions, including epilepsy, sleep apnoea, kidney, liver, heart or respiratory problems; take any other medicines or illegal drugs; or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before being given MIDAZOLAM INJECTION?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MIDAZOLAM INJECTION and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is MIDAZOLAM INJECTION given?

- Your doctor will decide what dose, how often and how long you will receive it. More instructions can be found in Section [4. How is MIDAZOLAM INJECTION given?](#) in the full CMI.

5. What should I know during treatment with MIDAZOLAM INJECTION?

Driving or using machines	<ul style="list-style-type: none">MIDAZOLAM INJECTION can affect driving and safe use of machinery and tools.
Drinking alcohol	<ul style="list-style-type: none">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.
Consuming caffeine	<ul style="list-style-type: none">Consuming caffeine (e.g. coffee, tea, energy drink, chocolate) may interfere with MIDAZOLAM INJECTION.Check with your doctor or nurse before consuming anything containing caffeine

For more information, see Section [5. What should I know during treatment with MIDAZOLAM INJECTION?](#) in the full CMI.

6. Are there any side effects?

Pain, redness or hardness around the site of injection; muscle stiffness or inflammation; nausea, vomiting; headache; drowsiness, tiredness, restlessness; dizziness, unsteadiness; hiccups; coughing; constipation; dry mouth or excessive saliva, acid taste in mouth; rash, itchiness; problems with vision; tingling or numbness of the hands or feet; feeling of extreme happiness, emotional, mood and behavioral disturbances; uncontrollable twitching or jerking movements; nightmares, abnormal dreams, sleep disturbance; difficulty with speaking; chest pain; trouble breathing; confusion, hallucinations; signs of allergic reaction (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).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MIDAZOLAM INJECTION* (migh-day-zuh-lam)

Active ingredient(s): *midazolam*

Consumer Medicine Information (CMI)

This leaflet provides important information about being given MIDAZOLAM INJECTION. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about being given MIDAZOLAM INJECTION.**

Where to find information in this leaflet:

1. [Why am I being given MIDAZOLAM INJECTION?](#)
2. [What should I know before being given MIDAZOLAM INJECTION?](#)
3. [What if I am taking other medicines?](#)
4. [How is MIDAZOLAM INJECTION given?](#)
5. [What should I know during treatment with MIDAZOLAM INJECTION?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given MIDAZOLAM INJECTION?

MIDAZOLAM INJECTION contains the active ingredient midazolam. MIDAZOLAM INJECTION belongs to a group of medicines called benzodiazepines.

MIDAZOLAM INJECTION is used as a sedative during short medical procedures, or it may be needed if you are in intensive care. MIDAZOLAM INJECTION may also be given to help induce anaesthesia before you are given another anaesthetic as part of an operation.

2. What should I know before being given MIDAZOLAM INJECTION?

Warnings

MIDAZOLAM INJECTION should not be given to you if:

- you are allergic to midazolam or any other benzodiazepines, or any of the ingredients listed at the end of this leaflet
- you have myasthenia gravis
- you have acute narrow angle glaucoma
- you are in shock, coma or in acute alcoholic intoxication with depression of vital signs.

Always check the ingredients to make sure you can be given this medicine.

Check with your doctor if you:

- have any other medical conditions such as epilepsy, sleep apnoea, kidney, liver and heart problems
- have a history of alcohol or drug abuse
- use illegal drugs, or medicines to treat insomnia anxiety, panic attacks, seizures or tension

- have breathing problems such as asthma, bronchitis, emphysema, or chronic obstructive pulmonary disease
- take any medicines for any other condition

Being given MIDAZOLAM INJECTION you may be at risk of developing certain side effects. It is important you understand these risks. See additional information under Section [6. Are there any side effects?](#)

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

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved, and any monitoring of your baby that maybe required if breastfeeding occurs

Use in the elderly

- There is an increased risk for falls and fractures in elderly patients using this type of medicine. The risk is increased if taking other sedatives.

3. What if I am taking other medicines?

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

Some medicines may interfere with MIDAZOLAM INJECTION and affect how it works. These include:

- ketoconazole, voriconazole, fluconazole, itraconazole and posaconazole, medicines for fungal infection.
- rifampicin, erythromycin, clarithromycin, telithromycin, and roxithromycin, medicines for bacterial infection.
- ritonavir and saquinavir, efavirenz, medicines for viral infection including HIV.
- diltiazem, verapamil and ticagrelor, medicines for heart problems.
- atorvastatin, medicine to lower cholesterol.
- fentanyl, ketamine, propofol, medicines for anesthesia or pain relief.
- fluvoxamine, nefazodone, and other medicines for mental health and emotional disorders.
- imatinib, lapatinib, idelalisib, aprepitant, netupitant, bicalutamide, everolimus, enzalutamide, vemurafenib, medicines used in cancer treatment.
- ciclosporine, medicine used after transplant.
- carbamazepine, phenytoin, valproic acid, medicines used to control epilepsy/seizure.
- medicines to treat strong pain.
- antihistamines, medicine used for allergies and colds.
- physostigmine used to treat glaucoma.

- St John's wort, echinacea, quercetin, panax ginseng, berberine - herbal medicines.

Check with your doctor or nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MIDAZOLAM INJECTION.

4. How is MIDAZOLAM INJECTION given?

How much is given

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 other medicines are being given at the same time.

How is MIDAZOLAM INJECTION given

- MIDAZOLAM INJECTION must only be given by a doctor or nurse.
- 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.
- It may be given as an injection into a vein or muscle, or given through slow infusion "drip" into a vein.

If you are given too much MIDAZOLAM INJECTION

As MIDAZOLAM INJECTION is given under the close supervision of your doctor, it is very unlikely that you will receive too much. Your condition will be carefully monitored following administration.

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

Tell your doctor or nurse immediately if you are concerned that you may have been given too much MIDAZOLAM INJECTION.

5. What should I know during treatment with MIDAZOLAM INJECTION?

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MIDAZOLAM INJECTION affects you.

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. MIDAZOLAM INJECTION has the potential to affect driving and has an associated risk with road safety.

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.**

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Consuming Caffeine

Consuming caffeine (e.g. coffee, tea, energy drink, chocolate) may interfere with MIDAZOLAM INJECTION. Check with your doctor or nurse before consuming anything containing caffeine.

Looking after your medicine

MIDAZOLAM INJECTION is stored in the pharmacy or on the hospital ward under the correct conditions.

Disposal of MIDAZOLAM INJECTION

The hospital staff will dispose of any leftover MIDAZOLAM INJECTION.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or nurse if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none"> • pain, redness or hardness around the site of injection • muscle stiffness or inflammation • nausea, vomiting • headache • drowsiness, tiredness, restlessness • dizziness, unsteadiness • hiccups • coughing • constipation • dry mouth or excessive saliva, acid taste in mouth • rash, itchiness • problems with vision • tingling or numbness of the hands or feet • feeling of extreme happiness • emotional, mood and behavioral disturbances • uncontrollable twitching or jerking movements • nightmares, abnormal dreams, sleep disturbance • difficulty with speaking • changes in libido 	<p>Speak to your doctor or nurse if you have any of these side effects and they worry you.</p>

Who distributes MIDAZOLAM INJECTION

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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Side effects	What to do
<ul style="list-style-type: none">• allergic reaction (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)• cardiac arrest, hypotension, bradycardia vasodilating effects, bigeminy, premature ventricular contractions, tachycardia, nodal rhythm, cardiovascular collapse, and vasovagal episode• chest pain• trouble breathing• confusion• hallucinations• dependance• loss of memory	Alert your doctor or nurse straight away, if you notice any of these side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side-effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or nurse before you decide to stop taking any of your medicines.

7. Product details

What MIDAZOLAM INJECTION contains

Active ingredient (main ingredient)	1 mg/mL or 5 mg/mL of midazolam (as hydrochloride)
Other ingredients (inactive ingredients)	sodium chloride sodium hydroxide hydrochloric acid Water for Injections.

Do not take this medicine if you are allergic to any of these ingredients.

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

What MIDAZOLAM INJECTION looks like

MIDAZOLAM INJECTION is a clear, colourless to pale yellow solution supplied in an ampoule.

5mg/1mL (AUST R 72213)

5mg/5mL (AUST R 72214)