

# B. BRAUN MIDAZOLAM

## 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 pharmacist.

### 1. Why am I given B. BRAUN MIDAZOLAM?

B. BRAUN MIDAZOLAM contains the active ingredient midazolam hydrochloride. B. BRAUN MIDAZOLAM is used as a sedative during some short medical procedures.

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

### 2. What should I know before I am given B BRAUN MIDAZOLAM?

Do not use if you have ever had an allergic reaction to midazolam or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with B. BRAUN MIDAZOLAM 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 am I given B. BRAUN MIDAZOLAM?

- B. BRAUN 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.
- 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.

More instructions can be found in Section [4. How am I given B. BRAUN MIDAZOLAM?](#) in the full CMI.

### 5. What should I know while given B. BRAUN MIDAZOLAM?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are receiving B. BRAUN MIDAZOLAM.</li><li>• Tell your doctor if you feel B. BRAUN MIDAZOLAM is not helping you.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take any other medicines whether they require a prescription or not without first telling your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate machinery until you know how B. BRAUN MIDAZOLAM affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not have any alcohol for at least 12 hours after you have been given B. BRAUN MIDAZOLAM.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• B. BRAUN MIDAZOLAM will be stored in the pharmacy or on the ward.</li><li>• It is kept in a cool dry place where the temperature stays below 25°C.</li><li>• It should be protected from light.</li></ul>

For more information, see Section [5. What should I know while given B. BRAUN MIDAZOLAM?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received B. BRAUN MIDAZOLAM. 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 a very small risk 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.

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.

# B. BRAUN MIDAZOLAM

Active ingredient(s): Midazolam

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I given B. BRAUN MIDAZOLAM?](#)
- [2. What should I know before I am given B. BRAUN MIDAZOLAM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given B. BRAUN MIDAZOLAM?](#)
- [5. What should I know while given B. BRAUN MIDAZOLAM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I given B. BRAUN MIDAZOLAM?

**B. BRAUN MIDAZOLAM contains the active ingredient midazolam.** B. BRAUN MIDAZOLAM belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

**B. BRAUN MIDAZOLAM is injected as a sedative during some short medical procedures.**

B. BRAUN 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 B. BRAUN MIDAZOLAM over several hours or days as a sedative.

B. BRAUN MIDAZOLAM can cause sedation, hypnosis, amnesia and/or anaesthesia, depending on the dose.

Your doctor, however, may have prescribed B. BRAUN MIDAZOLAM for another purpose.

**Ask your doctor if you have any questions about why B. BRAUN MIDAZOLAM has been prescribed for you.**

B. BRAUN MIDAZOLAM is only given by a doctor trained to use this medicine. If you will be receiving B. BRAUN 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.

## 2. What should I know before I am given B. BRAUN MIDAZOLAM?

### Warnings

**Do not use B. BRAUN MIDAZOLAM if:**

- you are allergic to midazolam, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have had an allergic reaction to any other benzodiazepine medicine.
- 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.

**Check with your doctor if you:**

- **have any other medical conditions including:**

- 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

-**take any medicines for any other condition**

-**if you drink alcohol or use illicit (illegal) drugs regularly**

- Be careful when drinking alcohol before receiving B. BRAUN MIDAZOLAM. Combining B. BRAUN 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 B. BRAUN MIDAZOLAM.
- B. BRAUN 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.

-**if you are allergic to any other medicines, foods, dyes or preservatives.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known whether B. BRAUN MIDAZOLAM is harmful to an unborn baby when given to a pregnant woman. If

there is a need to use B. BRAUN MIDAZOLAM when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

B. BRAUN MIDAZOLAM may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. B. BRAUN MIDAZOLAM is not recommended for use while breastfeeding.

## Children

Do not give B. BRAUN MIDAZOLAM to children.

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

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with B. BRAUN MIDAZOLAM and affect how it works.**

These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- anaesthetics
- fluvoxamine, nefazodone and other medicines for depression
- medicines to control fits such as sodiumvalproate
- medicines for allergies or colds such as antihistamines
- pain relievers
- chlorzoxazone and other muscle relaxants
- cimetidine, a medicine used to treat ulcers
- disulfiram a medicine used in alcohol abuse
- erythromycin and clarithromycin, common antibiotics
- diltiazem, verapamil and atorvastatin, medicines used to treat high blood pressure or heart conditions
- verapamil
- ketoconazole, fluconazole, posaconazole and itraconazole, medicines used to treat fungal infections
- ritonavir, saquinavir, and other HIV protease inhibitors, medicines used to treat HIV
- bicalutamide, a medicine used in the treatment of prostate cancer and for excessive hair loss particularly in women
- aprepitant, a medicine used for treatment of nausea (feeling sick) and vomiting associated with chemotherapy
- goldenseal, a complementary medicine

These medicines may be affected by B. BRAUN MIDAZOLAM or may affect how well B. BRAUN MIDAZOLAM works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also know of other medicines to be careful with or avoid while using B. BRAUN MIDAZOLAM.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect B. BRAUN MIDAZOLAM.**

## 4. How am I given B. BRAUN MIDAZOLAM ?

### 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.

### When is B. BRAUN MIDAZOLAM given

- B. BRAUN MIDAZOLAM may be given once before a medical procedure, or continuously by infusion for patients in an intensive care unit.
- B. BRAUN MIDAZOLAM will be stopped once there is no further need for sedation.

### How B. BRAUN MIDAZOLAM is given

- B. BRAUN 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.
- 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.

### For how long B. BRAUN MIDAZOLAM is given

B. BRAUN MIDAZOLAM may be given once before a medical procedure, or continuously by infusion for patients in an intensive care unit. B. BRAUN MIDAZOLAM will be stopped once there is no further need for sedation.

### If you have been given too much B. BRAUN MIDAZOLAM

If you think that you have been given too much B. BRAUN MIDAZOLAM, you may feel drowsy, tired, confused, dizzy, feel weak or become unconscious. You may need urgent medical attention.

**You should immediately:**

- tell your doctor or nurse.

## 5. What should I know while given B. BRAUN MIDAZOLAM?

### Things you should do

#### Tell your doctor straight away if you:

- feel B. BRAUN MIDAZOLAM is not helping you.

Remind any doctor, dentist, nurse or pharmacist you visit that you have been given B. BRAUN MIDAZOLAM.

### Things you should not do

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

### 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.

### Driving or using machines

#### Do not drive or use any machines or tools until you know how B. BRAUN MIDAZOLAM affects you.

B. BRAUN MIDAZOLAM may cause drowsiness, or dizziness fatigue, confusion and forgetfulness in some people and therefore may affect alertness. Make sure you know how you react to B. BRAUN 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.

### Drinking alcohol

#### Tell your doctor if you drink alcohol.

Do not have any alcohol for at least 12 hours after you have been given B. BRAUN MIDAZOLAM.

### Looking after your medicine

- B. BRAUN MIDAZOLAM 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.

## 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 pharmacist if you have any further questions about side effects.

All medical procedures which involve the use of an anaesthetic have a very small risk 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.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• drowsiness, tiredness, reduced alertness</li> <li>• dizziness, unsteadiness, feeling of loss of consciousness</li> <li>• loss of memory, inattentiveness, confusion, lack of concentration</li> <li>• headache, hangover feeling in the morning</li> <li>• slurred speech</li> <li>• unpleasant dreams</li> <li>• blurred vision</li> <li>• pain, redness or hardness at the injection site</li> <li>• muscle stiffness or inflammation of the vein,</li> <li>• coughing, hiccups</li> <li>• feeling sick with or without vomiting</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

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

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• difficulty breathing or wheezing</li> <li>• changes in pulse rate and blood pressure</li> <li>• sudden anxiety or excitation</li> <li>• hallucinations, unusual mood or delusions</li> <li>• severe sleep disturbances</li> <li>• allergic reaction - sudden signs such as rash, itching or hives on the skin, swelling of the face, lips tongue which may cause difficulty in swallowing or breathing and other parts of the body,</li> <li>• pale skin, a weak and rapid pulse, or loss of consciousness. Additionally, you may experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

#### Tell your doctor or pharmacist 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/reporting-problems](http://www.tga.gov.au/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 pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What B. BRAUN MIDAZOLAM contains

<b>Active ingredient (main ingredient)</b>	Midazolam
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium chloride</li><li>• hydrochloric acid</li><li>• water for injections.</li></ul>
<b>Potential allergens</b>	None

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

B. BRAUN MIDAZOLAM ampoules 5 mg/5 mL come in packs of 10.

B. BRAUN MIDAZOLAM ampoules 5 mg/1 mL come in packs of 10.

B. BRAUN MIDAZOLAM ampoules 15 mg/3 mL come in packs of 10.

B. BRAUN MIDAZOLAM ampoules 50mg/10 mL come in packs of 20.

B. BRAUN MIDAZOLAM bottles 50 mg/50 mL and 100 mg/100 mL come in packs of 10.

### What B. BRAUN MIDAZOLAM looks like

B. BRAUN MIDAZOLAM is a clear colourless to yellowish solution.

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- B. BRAUN MIDAZOLAM 5 mg/5 mL Solution for Injection ampoule (AUST R 225700)
- B. BRAUN MIDAZOLAM 5 mg/1 mL Solution for Injection ampoule (AUST R 225699)
- B. BRAUN MIDAZOLAM 15 mg/3 mL Solution for Injection ampoule (AUST R 225698)
- B. BRAUN MIDAZOLAM 50 mg/10 mL Solution for Injection ampoule (AUST R 225701)

- B. BRAUN MIDAZOLAM 50 mg/50 mL Injection, Intravenous Infusion bottle (AUST R 225697)
- B. BRAUN MIDAZOLAM 100 mg/100 mL Injection, Intravenous Infusion bottle (AUST R 225696)

### Who distributes B. BRAUN MIDAZOLAM

B. Braun Australia Pty Ltd  
Level 5, 7-9 Irvine Place  
Bella Vista NSW 2153  
Australia

Toll free number: 1800 251 705

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