

# MIDAZOLAM ACCORD

## 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 being given Midazolam Accord?

Midazolam Accord contains the active ingredient midazolam. Midazolam Accord can cause sedation, hypnosis, amnesia and/or anaesthesia, depending on the dose, and may be given to you to produce sleepiness or drowsiness, or to relieve anxiety.

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

### 2. What should I know before I am given Midazolam Accord?

Do not use if you have ever had an allergic reaction to an any medicine containing midazolam, any other benzodiazepine medicine, or any of the ingredients listed at the end of this leaflet.

You should also not be given it if you have severe muscle weakness (myasthenia gravis), acute narrow angle glaucoma or if you are suffering from shock, coma or acute alcoholic intoxication.

**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 use Midazolam Accord?](#) in the full CMI.

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

Some medicines may interfere with Midazolam Accord and affect how it works.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given Midazolam Accord?

Midazolam Accord is an injection and will be given to you by your doctor or nurse.

More instructions can be found in Section [4. How do I use Midazolam Accord?](#) in the full CMI.

### 5. What should I know while being given Midazolam Accord?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Midazolam Accord</li><li>• Tell your doctor before you take any other medicines - whether they require a prescription or not</li><li>• Do not drink alcohol for at least 12 hours before being given Midazolam Accord.</li></ul>
<b>Driving or using machines</b>	Do not drive or operate machinery until you know how Midazolam Accord affects you. Midazolam Accord may cause drowsiness or dizziness in some people and therefore may affect alertness.

For more information, see Section [5. What should I know while I am being given Midazolam Accord?](#) in the full CMI.

### 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.

The serious side effects are:

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

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 ACCORD

Active ingredient: *midazolam*

## Consumer Medicine Information (CMI)

This leaflet provides important information about Midazolam Accord. **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 Midazolam Accord.**

Where to find information in this leaflet:

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

## 1. Why am I using Midazolam Accord?

**Midazolam Accord contains the active ingredient midazolam.** Midazolam belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals. Midazolam Accord can cause sedation, hypnosis, amnesia and/or anaesthesia, depending on the dose.

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

Midazolam Accord 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 Accord over several hours or days as a sedative.

Your doctor, however, may have prescribed Midazolam Accord for another purpose.

Midazolam Accord is only given by a doctor trained to use this medicine.

If you will be receiving Midazolam Accord during surgery, your doctor will give you the medicine and closely follow your progress.

## 2. What should I know before I am given Midazolam Accord?

### Warnings

**You must not be given Midazolam Accord if:**

- You have ever 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.

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

Do not give Midazolam Accord to children.

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

### Before you are given it

Your doctor must know about all the following before you receive Midazolam Accord:

#### 1. If you have any health problems including:

- liver, kidney, heart or lung disease
- high or low blood pressure
- mental disorders including; depression, psychosis or schizophrenia
- epilepsy (fits or convulsions)

#### 2. If you drink alcohol regularly:

Be careful when drinking alcohol before receiving Midazolam Accord. Combining Midazolam Accord 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 Accord.

#### 3. If you are allergic to any other medicines, foods, dyes or preservatives.

### Pregnancy and breastfeeding

It is not known whether Midazolam Accord is harmful to an unborn baby when given to a pregnant woman. If there is a need to use Midazolam Accord when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

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

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

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

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

- other sleeping tablets, sedatives or tranquillisers
- anaesthetics
- medicines for depression
- medicines to control fits e.g. sodium valproate
- medicines for allergies or colds e.g. antihistamines
- pain relievers
- muscle relaxants
- cimetidine (Tagamet®, Magicul®), a medicine used to treat ulcers
- disulfiram (Antabuse®), a medicine used in alcohol abuse
- erythromycin, a common antibiotic
- diltiazem (Cardizem®)
- verapamil (Isoptin®, Anpec®, Cordilox®, Veracaps®)
- ketoconazole, fluconazole and itraconazole
- ritonavir and Saquinavir

These medicines may be affected by Midazolam Accord or may affect how well Midazolam Accord 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 Midazolam Accord.

**If you have not told your doctor about any of the above, tell them before you receive Midazolam Accord.**

#### 4. How will I be given Midazolam Accord?

Midazolam Accord 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.

#### How long is Midazolam Accord given for

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

#### If you are given too much (overdose)

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

#### 5. What should I know while I am being given Midazolam Accord?

##### Things you should do

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

Be careful if you are elderly, unwell 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.

##### Things you should not do

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

#### Driving or using machines

**Be careful driving or operating machinery until you know how Midazolam Accord affects you.**

Midazolam Accord may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to Midazolam Accord before you drive a car or operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

#### Looking after your medicine

The hospital will store Midazolam Accord under the correct conditions. Any unused medicine will be disposed of appropriately by the medical staff.

#### Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Midazolam Accord that may be left over.

#### 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 Midazolam Accord.

In addition to the beneficial effects of Midazolam Accord it is possible that unwanted effects will occur during treatment, even when it is used as intended. 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.

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.

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

##### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>• drowsiness, tiredness</li> <li>• dizziness, unsteadiness</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 common side effects and they worry you</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• difficulty breathing</li><li>• changes in pulse rate and blood pressure</li><li>• sudden anxiety or excitation</li><li>• hallucinations or delusions</li><li>• severe sleep disturbances</li></ul>	<b>Tell your doctor immediately or go to casualty at your nearest hospital</b>

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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor, nurse or pharmacist if you do not understand anything in this list.

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

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects online at <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 Midazolam Accord contains

<b>Active ingredient (main ingredient)</b>	Midazolam
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Concentrated hydrochloric acid Sodium hydroxide Water for injections

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

### What Midazolam Accord looks like

Midazolam Accord is a clear, colourless to pale yellow, isotonic solution supplied in glass ampoules or syringes. There are four ampoule presentations: 5 mg/5 mL (AUST R 207239), 5 mg/1 mL (AUST R 207241), 15 mg/3 mL (AUST R 207245) and 50 mg/10 mL (AUST R 207225) and two syringe presentations: 5 mg/5mL (AUST R 329165) and 50 mg/10 mL (AUST R 329163).

## Who distributes Midazolam Accord

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne, VIC, 3000  
Australia

This leaflet was prepared in October 2021.