

MIDAZOLAM ACCORD

Midazolam Injection 5 mg/5 mL, 5 mg/1 mL, 15 mg/3 mL and 50 mg/10 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Midazolam Accord. It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

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

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Midazolam Accord is used for

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.

Midazolam Accord 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.

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

Ask your doctor if you have any questions about why Midazolam Accord has been prescribed for you.

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.

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

Before you are given Midazolam Accord

When you must not be given it

- **you have had an allergic reaction to Midazolam Accord, 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 are pregnant or plan to become pregnant

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.

2. if you are breastfeeding or plan to breastfeed

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. if you have any other 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)

4. 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.

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

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.

How Midazolam Accord is given

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.

For how long Midazolam Accord is given

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.

While you are given Midazolam Accord

Things you must do

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 Accord is not helping you.

Things you must not do

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. 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.

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

Things to be careful of

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.

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:

- 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 immediately or go to casualty at your nearest hospital if you notice any of the following:

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

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.

Storage

Stored below 25°C. Protect from Light.

Any unused medicine must be disposed of appropriately by the medical staff.

Product Description

What it looks like

Midazolam Accord is a clear, colourless to pale yellow, isotonic solution.

In clear glass ampoules it is available in 4 presentations; 5 mg/5 mL, 5 mg/1 mL, 15 mg/3 mL and 50 mg/10 mL in 10 packs.

In syringes it is available in 2 presentations; 5 mg/5 mL and 50 mg/10 mL in packs of 1.

Ingredients

Active ingredient:
midazolam

Inactive ingredients:
sodium chloride
hydrochloric acid, concentrated
sodium hydroxide
water for injections

It does not contain a preservative.

Name and Address of the Sponsor

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

Australian Registration Numbers

5 mg/5 mL: AUST R 207239

5 mg/1 mL: AUST R 207241

15 mg/3 mL: AUST R 207245

50 mg/10 mL: AUST R 207225

5 mg/5 mL syringe: AUST R
329165

50 mg/10 mL syringe: AUST R
329163

Date of Preparation

This leaflet was prepared on 05 May 2020.