

MIDAZOLAM Alphapharm

contains the active ingredient midazolam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MIDAZOLAM Alphapharm.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking MIDAZOLAM Alphapharm against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What MIDAZOLAM Alphapharm is used for

MIDAZOLAM Alphapharm may be injected as a sedative during some short medical procedures.

MIDAZOLAM Alphapharm 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 Alphapharm over several hours or days as a sedative.

MIDAZOLAM Alphapharm belongs to a group of medicines known as benzodiazepines.

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

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

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

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

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

When you must not receive it

Do not use MIDAZOLAM Alphapharm if you have an allergy to:

- **allergy to any medicine containing midazolam**
- **allergy to any of the ingredients listed at the end of this leaflet**

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

If you are not sure whether you should be given MIDAZOLAM Alphapharm, talk to your doctor.

Do not give MIDAZOLAM Alphapharm to children.

The safety or effectiveness of MIDAZOLAM Alphapharm in children less than eight years of age have not been established.

Before you receive 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 medical conditions:

- **severe muscle weakness, also known as myasthenia gravis**
- **a condition called acute narrow angle glaucoma**
- **suffering from shock**
- **coma or acute alcoholic intoxication**

Tell your doctor if you have or have had any of the following conditions:

1. **are pregnant or plan to become pregnant**

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

2. **are breastfeeding or plan to breastfeed**

MIDAZOLAM Alphapharm may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby.

MIDAZOLAM Alphapharm is not recommended for use while breastfeeding.

3. **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. **drink alcohol regularly**

Be careful when drinking alcohol before receiving MIDAZOLAM Alphapharm. Combining MIDAZOLAM Alphapharm 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 Alphapharm.

If you have not told your doctor about any of the above, tell him/her before you start taking MIDAZOLAM Alphapharm.

Taking other medicines

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

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

- other sleeping tablets, sedatives or tranquillisers
- anaesthetics
- medicines for depression
- medicines to control fits such as sodium valproate
- medicines for allergies or colds such as 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 Alphapharm or may affect how well MIDAZOLAM Alphapharm 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.

How MIDAZOLAM Alphapharm is given

MIDAZOLAM Alphapharm may be given to you as an injection into a vein or muscle, or through an intravenous infusion in an intensive care unit, by a doctor or a nurse.

Other medications may also be given at the same time.

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.

For how long this medicine is given for

MIDAZOLAM Alphapharm may be given once before a medical procedure, or continuously by infusion for patients in an intensive care unit.

MIDAZOLAM Alphapharm will be stopped once there is no further need for sedation.

If you take too much (overdose)

Tell the doctor or nurse on duty if you think you have been given an overdose of MIDAZOLAM Alphapharm.

However, if you are given too much MIDAZOLAM Alphapharm, you may experience side effects such as drowsiness, tiredness, confusion, dizziness, weakness or unconsciousness.

Ask your doctor if you have any concerns.

Your doctor has information on how to recognise and treat an overdose.

While you are given MIDAZOLAM Alphapharm

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 Alphapharm not helping you.

Things you must not do

Do not drive or operate machinery until you know how MIDAZOLAM Alphapharm affects you.

MIDAZOLAM Alphapharm may cause drowsiness or dizziness in some people and therefore may affect alertness.

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

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 Alphapharm.

In addition to the beneficial effects of MIDAZOLAM Alphapharm, 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.

Do not be alarmed by the following list 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 if you notice any of the following and they worry you:

- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- nausea with or without vomiting
- muscle stiffness or inflammation of the vein
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams

- blurred vision
- pain, redness or hardness at the injection site
- drowsiness, tiredness
- coughing, hiccups

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

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

These above list includes serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

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

After using MIDAZOLAM Alphapharm

Storage

MIDAZOLAM Alphapharm will be stored in the pharmacy or on the ward. The ampoule is kept in a cool, dry place away from sunlight, where the temperature stays below 25°C. The ampoule should not be stored in the refrigerator.

If you have any further questions on MIDAZOLAM Alphapharm, or are unsure of the information given above, please see your doctor or nurse, who will be able to assist you.

Product description

What it looks like

MIDAZOLAM Alphapharm is a clear colourless solution containing MIDAZOLAM in the following strengths:

- 5 mg/ 5 mL ampoule
- 5 mg/mL ampoule
- 15 mg/ 3 mL ampoule
- 50 mg/ 10 mL ampoule

Ingredients

Active Ingredients

- MIDAZOLAM Alphapharm 5 mg/ 5 mL
- MIDAZOLAM Alphapharm 5 mg/mL
- MIDAZOLAM Alphapharm 15 mg/ 3 mL
- MIDAZOLAM Alphapharm 50 mg/ 10mL

Inactive ingredients

- sodium chloride
- glucose
- water for injection
- small amounts of hydrochloric acid and sodium hydroxide to adjust the acidity of the solution.

Supplier

Alphapharm Pty Limited

(ABN 93 002 359 739)

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Medical Information

Phone: 1800 028 365

Australian registration number

MIDAZOLAM Alphapharm 5 mg/ 5 mL - AUST R 160206

MIDAZOLAM Alphapharm 5 mg/mL - AUST R 160207

MIDAZOLAM Alphapharm 15 mg/ 3 mL - AUST R 160205

MIDAZOLAM Alphapharm 50 mg/ 10mL - AUST R 160208

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