

MIDAZOLAM VIATRIS

Midazolam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MIDAZOLAM VIATRIS.

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 VIATRIS 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 VIATRIS is used for

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

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

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

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

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

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

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

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

When you must not receive it

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

- **any medicine containing midazolam**
- **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

Do not use MIDAZOLAM VIATRIS if:

- 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 VIATRIS, talk to your doctor.

Do not give MIDAZOLAM VIATRIS to children.

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

Before you receive it

Tell your doctor if you have or have had any of the following before you receive MIDAZOLAM VIATRIS:

1. if you are pregnant or plan to become pregnant

MIDAZOLAM VIATRIS is not recommended for use in pregnant women, especially in the third (last) trimester or during labour. If there is a need to use MIDAZOLAM VIATRIS 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 VIATRIS may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. MIDAZOLAM VIATRIS 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)
- history of alcohol or drug abuse

4. if you drink alcohol regularly or use illicit (illegal) drugs regularly

MIDAZOLAM VIATRIS can cause physical dependency, especially if you have a history of drug or alcohol abuse, when used long-term. Your dose maybe reduced gradually to overcome this effect.

5. if you have allergies to any other medicines, foods, preservatives or dyes.

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

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 VIATRIS may interfere with each other. These medicines include:

- other sleeping tablets, sedatives or tranquillisers

- anaesthetics
- medicines for depression such as fluvoxamine and nefazodone
- 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 and clarithromycin, common antibiotic
- diltiazem (Cardizem[®]), verapamil (Isoptin[®], Anpec[®], Cordilox[®], Veracaps[®]), medicines used to treat high blood pressure
- atorvastatin
- ketoconazole, fluconazole and itraconazole or other medicines used to treat fungal infections
- ritonavir and saquinavir and other HIV protease inhibitors
- Bicalutamide, medicine used in the treatment of prostate cancer and 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 MIDAZOLAM VIATRIS or may affect how well MIDAZOLAM VIATRIS 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 VIATRIS is given

MIDAZOLAM VIATRIS 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.

How long is MIDAZOLAM VIATRIS given for

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

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

If you have been given too much (overdose)

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

However, if you are given too much MIDAZOLAM VIATRIS, 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 VIATRIS

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 VIATRIS not helping you.

Things you must not do

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

MIDAZOLAM VIATRIS 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 MIDAZOLAM VIATRIS 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 VIATRIS.

Things to be careful of

Be careful if you are elderly, drinking alcohol, 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 VIATRIS.

In addition to the beneficial effects of MIDAZOLAM VIATRIS, 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.

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
- drowsiness, tiredness
- loss of memory, inattentiveness, confusion, lack of concentration

- muscle stiffness or inflammation of the vein
- slurred speech
- unpleasant dreams
- blurred vision
- pain, redness or hardness at the injection site
- constipation
- coughing, hiccups
- nausea with or without vomiting

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, unusual mood or delusions
- severe sleep disturbances
- 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

The 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.

Ask your doctor or pharmacist if you do not understand anything on this list.

Do not be alarmed by this list of side effects.

You may not experience any of them

After using MIDAZOLAM VIATRIS

Storage

MIDAZOLAM VIATRIS 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 VIATRIS, 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 VIATRIS 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 VIATRIS 5 mg/ 5 mL
- MIDAZOLAM VIATRIS 5 mg/mL
- MIDAZOLAM VIATRIS 15 mg/ 3 mL
- MIDAZOLAM VIATRIS 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

MIDAZOLAM VIATRIS is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration number

- MIDAZOLAM VIATRIS 5 mg/ 5 mL - AUST R 160206
- MIDAZOLAM VIATRIS 5 mg/mL - AUST R 160207
- MIDAZOLAM VIATRIS 15 mg/ 3 mL - AUST R 160205
- MIDAZOLAM VIATRIS 50 mg/ 10mL - AUST R 160208

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