

MIDAZOLAM VIATRIS

Midazolam 1 mg/mL and 5 mg/mL ampoules



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 risks and benefits. Your doctor has weighed the risks of you taking MIDAZOLAM VIATRIS against the benefits they expect it will have for you.

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

Keep this leaflet. You may need to read it again.

What MIDAZOLAM VIATRIS is used for

MIDAZOLAM VIATRIS is used for the following.

- may be given as a sedative during some short medical procedures.
- may be given before an operation to produce sleepiness or drowsiness and to relieve anxiety. It may also be used in combination with other anaesthetic agents to keep you asleep during an operation.
- If you are in an intensive care unit, you may receive MIDAZOLAM VIATRIS as a sedative.

This medicine belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

MIDAZOLAM VIATRIS can cause sedation (sleepiness), short term amnesia (no memory of events around the time you are given MIDAZOLAM VIATRIS, and/or anaesthesia (heavy sleep for surgery) depending on the dose you are given.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you are given MIDAZOLAM VIATRIS

When you must not use it

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

- any medicine containing midazolam or any other benzodiazepine medicine.
- 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 have MIDAZOLAM VIATRIS if you:

- have myasthenia gravis (severe muscle weakness)
- have a condition called acute narrow angle glaucoma

- are suffering from shock, coma or alcoholic intoxication.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you use 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:

- liver, kidney, heart or lung disease
- breathing difficulties including sleep apnoea
- any long-term illness that is making you weak
- high or low blood pressure
- history of alcohol or drug abuse
- you have severe muscle weakness, known as myasthenia gravis
- mental disorders including; depression, psychosis or schizophrenia
- epilepsy (fits or convulsions)

Tell your doctor if you are taking opioids, a class of medicines used to treat pain.

Opioids include medicines such as oxycodone, fentanyl, hydromorphone, tramadol and taking them at the same time as MIDAZOLAM VIATRIS has the potential to cause very serious side effects.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

There is an increased risk of miscarriage from benzodiazepine exposure during pregnancy. Your doctor can discuss with you the risks and benefits involved.

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

Dependency

MIDAZOLAM VIATRIS can cause physical dependency, especially if you have a history of alcohol or drug abuse, when used long-term (for example, when used in an intensive care unit for long periods of time). Your dose may be reduced gradually to overcome this effect.

Taking other medicines

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

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

- other sleeping tablets, sedatives or tranquilisers
- anaesthetics
- fluvoxamine, nefazodone and other medicines for depression
- medicines for allergies or colds such as antihistamines
- pain relievers
- chlorzoxazone and other muscle relaxants
- diltiazem, verapamil and atorvastatin, medicines used to treat high blood pressure or heart conditions
- bicalutamide, a medicine used in the treatment of prostate cancer
- Aprepitant, a medicine used for treatment of nausea and vomiting associated with chemotherapy
- Goldenseal, a complementary medicine
- erythromycin, clarithromycin and rifampicin which are antibiotics
- sodium valproate, an epilepsy medicine
- Valproic acid, an epilepsy medicine
- ketoconazole, voriconazole, fluconazole and itraconazole, antifungal

medicines

- ritonavir, saquinavir and other HIV/AIDS medicines
- boceprevir and telaprevir, Hepatitis C medicines
- cimetidine and ranitidine, medicines used to treat ulcers and indigestion
- opioids
- ticagrelor, a medicine used to lower your risk of stroke
- St. John's Wort, a herbal medicine
- Echinacea purpurea root extract

These medicines may be affected by MIDAZOLAM VIATRIS or may affect how well it 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

How much is given

MIDAZOLAM VIATRIS solution for injection may be given to you as an injection into a vein or muscle, or as an infusion into a vein. Other medications may also be given at the same time.

In children MIDAZOLAM VIATRIS solution for injection can also be given as drops into the mouth or nose, or rectally (into the back passage) using a syringe without a needle.

Your doctor will adjust the dose necessary for you. This depends on which medical procedure you are having, your age, weight, general health, and the way in which the medicine is being given to you.

How long is it given

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

If you use too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MIDAZOLAM VIATRIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling sick (nausea), vomiting, dizziness, slowing of breathing, slowing of heart rate, drowsiness, confusion, loss of muscle tone and coordination, tiredness, loss of muscle tone and coordination, difficulty in speaking, uncontrollable eye movements, loss of normal reflexes and coma. A few people may become over-excited and/or angry.

If you are not sure what to do, ask your doctor or pharmacist.

While you are having 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 is 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, dizziness, fatigue, confusion, hallucinations and forgetfulness 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. If you have not had enough sleep or have been drinking alcohol, you are likely to be less alert.

Things to be careful of

Particular care should be taken 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.

If you drink alcohol these effects could be worse.

Drinking alcohol is not recommended after you have been given MIDAZOLAM VIATRIS.

Ask your doctor or pharmacist how long you should avoid alcohol for.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received MIDAZOLAM VIATRIS.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 60 years of age you may have an increased chance of getting side effects. **Do not be alarmed by the following lists 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 or pharmacist if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness
- confusion, lack of concentration, feeling

disorientated, restless or irritable

- mood changes
- anxiety, nightmares, hallucinations, inappropriate behaviour
- headache
- hiccups
- feeling sick with or without vomiting
- constipation
- dry mouth
- coughing
- involuntary (uncontrollable) movements
- rash or itching
- muscle stiffness
- redness or pain at the site of the injection
- older patients, and those taking other sedatives or alcohol may be more likely to fall and suffer fractures

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

- sudden anxiety or excitation
- feeling faint
- irregular pulse
- feeling agitated, aggressive or angry
- hallucinations or delusions
- convulsions
- 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
- shortness of breath, wheezing or trouble breathing

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After taking MIDAZOLAM VIATRIS

Storage

MIDAZOLAM VIATRIS solution for injection will be stored in the pharmacy or on the ward out of reach of children. It is kept in a cool dry place where the temperature stays below 25°C. It should be protected from light.

Product description

What it looks like

MIDAZOLAM VIATRIS solution for injection is a clear, colourless solution, packaged in a clear colourless ampoule.

Ingredients

MIDAZOLAM VIATRIS contains 5 mg/ 5 mL or 15 mg/ 3 mL of midazolam as the active ingredient.

It also contains:

- sodium chloride
- hydrochloric acid
- sodium hydroxide
- water for injection

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

MIDAZOLAM VIATRIS is distributed in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

22 November 2024
(Based on datasheet dated 22
November 2024)