

Midazolam-Clarix

Midazolam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Midazolam-Clarix.

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 using Midazolam-Clarix 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-Clarix is used for

Midazolam-Clarix may be injected as a sedative during some short medical procedures. Midazolam-Clarix 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-Clarix over several hours or days as a sedative.

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

Your doctor, however, may have prescribed Midazolam-Clarix for another purpose. **Ask your doctor if you have any questions about why Midazolam-Clarix has been prescribed for you.**

Midazolam-Clarix is only given by a doctor trained to use this medicine. If you will be receiving Midazolam-Clarix 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 receive Midazolam-Clarix

Do not use Midazolam-Clarix if

- you have 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-Clarix, talk to your doctor.

Do not give Midazolam-Clarix to children.

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

Before you receive it

Your doctor must know about all the following before you receive Midazolam-Clarix.

1. **if you are pregnant or plan to become pregnant.** It is not known whether Midazolam-Clarix is harmful to an

unborn baby when given to a pregnant woman. If there is a need to use Midazolam-Clarix 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-Clarix may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Midazolam-Clarix 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.** Be careful when drinking alcohol before receiving Midazolam-Clarix. Combining Midazolam-Clarix 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-Clarix.
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 healthfood shop.

Some medicines and Midazolam-Clarix 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, a medicine used to treat ulcers
- disulfiram a medicine used in alcohol abuse
- erythromycin, a common antibiotic
- diltiazem and verapamil, medicines used to treat high blood pressure or heart conditions
- verapamil
- ketoconazole, fluconazole and itraconazole, medicines used to treat fungal infections
- ritonavir and saquinavir, medicines used to treat HIV

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

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

How Midazolam-Clarix is given

Midazolam-Clarix 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-Clarix is given

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

If you have been given too much (overdose)

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

While you are taking Midazolam-Clarix

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-Clarix is not helping you.

Things you must not do

Do not drive or operate machinery until you know how midazolam affects you. Midazolam-Clarix may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to Midazolam-Clarix 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-Clarix.

Things to be careful of

Be careful if you are elderly, unwell, drinking alcohol 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-Clarix.

In addition to the beneficial effects of Midazolam-Clarix 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 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.

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

Midazolam Claris is available as:

5 mg/5 mL: packs of 5, 10 and 25 ampoules.
AUST R 216025

5 mg/1 mL: packs of 5, 10 and 25 ampoules.
AUST R 216024

15 mg/3 mL: packs of 5, 10 and 25 ampoules. AUST R 216026

50 mg/10 mL: packs of 5, 10 and 25 ampoules. AUST R 216027

Sponsor

Baxter Healthcare Pty Ltd
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Date of preparation: 03/12/2018

After taking Midazolam-Claris

Storage

Midazolam-Claris will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 30 °C. It should be protected from light.

Product Description

What Midazolam-Claris looks like

Midazolam-Claris is a clear colourless to yellowish solution.

Ingredients

Active ingredient - midazolam

- each ampoule of Midazolam-Claris 5 mg/5 mL and 5 mg/1 mL contains 5 mg midazolam
- each ampoule of Midazolam-Claris 15 mg/3 mL contains 15mg midazolam
- each ampoule of Midazolam-Claris 50 mg/10 mL contains 50 mg midazolam

Inactive ingredients