

PACKAGE LEAFLET: INFORMATION FOR THE USER

Midazolam 1mg/ml Injection

Midazolam Hydrochloride

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Midazolam Injection is and what it is used for
2. What you need to know before you are given Midazolam Injection
3. How Midazolam Injection will be given
4. Possible side effects
5. How to store Midazolam Injection
6. Contents of the pack and other information

1. What Midazolam Injection is and what it is used for

Midazolam belongs to a group of medicines known as benzodiazepines. It is a short-acting medicine that is used to induce sedation (a very relaxed state of calm, drowsiness or sleep) and relieves anxiety and muscle tension.

This medicine is used for:

- Conscious sedation (an awake but very relaxed state of calm or drowsiness during a medical test or procedure) in adults and children.
- Sedation of adults and children, in intensive care units.
- Anaesthesia in adults, used alone or with other medicines.
- Premedication (medicine used to cause relaxation, calm and drowsiness before an anaesthetic) in adults and children.

2. What you need to know before you are given Midazolam Injection

You should not be given Midazolam Injection if:

- you are allergic to Midazolam or to medicines like Midazolam (benzodiazepines), or to any of the other ingredients of this medicine, (listed in section 6).
- you suffer from breathing difficulties.

You must not be given Midazolam Injection if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Children and babies

If your child is going to be given this medicine:

- It is particularly important to tell your doctor or nurse if your child has cardiovascular disease (heart problems). Your child will be carefully monitored and the dose will be adjusted specially.
- Children must be carefully monitored. For infants and babies under 6 months this will include monitoring of breathing and oxygen levels.

Adults

Before Midazolam Injection is given, let your doctor or nurse know if:

- You are over 60 years of age.
- You have a long term illness (such as breathing problems or kidney, liver or heart problems).
- You are debilitated (have an illness that makes you feel very weak, run down and short of energy).
- You have myasthenia gravis (a neuromuscular disease causing muscle weakness).
- You regularly drink large amounts of alcohol or you have had problems with alcohol use in the past. Alcohol can increase the effects of Midazolam Injection, possibly leading to severe sedation that could result in coma or death.
- You regularly take recreational drugs or you have had problems with drug use in the past.
- You are pregnant or think you may be pregnant (see 'Pregnancy and breast-feeding').

If any of the above apply to you, or if you are not sure, talk to your doctor or nurse before you are given Midazolam Injection.

Other medicines and Midazolam Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines.

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved. In particular, tell your doctor or nurse if you are taking any of the following medicines:

- tranquilisers (for anxiety or to help you sleep)
- hypnotics (medicines to make you sleep)
- sedatives (to make you feel calm or sleepy)
- antidepressants (medicines for depression)
- narcotic analgesics (very strong pain killers) e.g. Fentanyl
- antihistamines (used to treat allergies)
- medicines used to treat fungal infections (ketconazole, voriconazole, fluconazole, itraconazole, posaconazole)
- medicines used to treat bacterial infections such as erythromycin, clarithromycin, roxithromycin and telithromycin.
- diltiazem (used to treat high blood pressure)
- medicines used to treat HIV called protease inhibitors (such as saquinavir)
- medicines for hepatitis C (protease inhibitors such as boceprevir and telaprevir)
- atorvastatin (used to treat high cholesterol)
- rifampicin (used to treat mycobacterial infections such as tuberculosis)
- the herbal medicine St John's Wort
- medicines used to treat chest pains e.g. verapamil
- medicines used to treat epilepsy (fits) such as phenytoin and carbamazepine
- medicines used to treat serious mental disorders (antipsychotics) such as chlorpromazine, haloperidol and clozapine

If any of the above apply to you, or if you are not sure, talk to your doctor or nurse before you are given Midazolam Injection.

Concomitant use of Midazolam Injection and opioids (strong pain killers, medicines

for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Midazolam Injection together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Operations

If you are going to have an inhaled anaesthetic (one that you breathe in) for an operation or for dental treatment, it is important to tell your doctor or dentist that you have been given Midazolam Injection.

Midazolam Injection with alcohol

Do not drink alcohol if you have been given Midazolam Injection. This is because alcohol can increase the sedative effect of Midazolam Injection and may cause problems with your breathing.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Your doctor will decide if this medicine is suitable for you.

Midazolam Injection may harm your unborn baby when used in early pregnancy. When high doses are administered during late pregnancy, labour or caesarean section, you might have an inhalation risk and your baby might have an irregular heartbeat, state of low muscle tone (hypotonia), feeding difficulties, a low body temperature and difficulty in breathing. With prolonged administration during late pregnancy, your baby may develop a physical dependence and risk of withdrawal symptoms after birth.

Do not breast-feed for 24 hours after being given Midazolam Injection. This is because Midazolam Injection may pass into your breast milk.

Driving and using machines

This medicine can affect your ability to drive and operate machinery as it may make you sleepy or dizzy.

- Do not drive or use machinery until you are completely recovered. Your doctor should advise you when you can start these again.
 - Midazolam Injection may make you feel sleepy, forgetful or affect your concentration and co-ordination. This may affect your performance at skilled tasks such as driving or using machines.
 - You should always be taken home by a responsible adult after your treatment.
 - It is an offence to drive if this medicine affects your ability to drive.
 - However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely.
- Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Important information about some of the ingredients of Midazolam Injection

This medicine contains 3.46 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.17% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your pharmacist or doctor if you need Midazolam Injection on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How Midazolam Injection will be given

Midazolam Injection should be given only by experienced healthcare professionals (doctor or nurse). It should be given in a place (hospital, clinic or surgery) equipped to monitor and support the patient's breathing, heart and circulation (cardiovascular function) and recognise the signs of and manage the expected side effects of anaesthesia.

Normal adult dose

Your doctor will decide on a suitable dose for you. The dose you are given will depend on why you are being treated and the type of sedation needed. Your weight, age, your state of health, how you respond to Midazolam Injection and whether other medicines are needed at the same time will also influence the dose that you are given.

If you need strong painkillers, you will be given these first and then be given Midazolam Injection. The dose will be adjusted specially for you.

Midazolam Injection may be given to you in one of four different ways:

- by slow injection into a vein (intravenous injection)
- through a tube into one of your veins (intravenous infusion)
- by injection into a muscle (intramuscular injection)
- into your back passage (rectum).

You should always be taken home by a responsible adult after your treatment.

Children and babies

- In infants and babies under 6 months of age Midazolam Injection is only recommended for sedation in intensive care units. The dose will be given gradually into a vein.
- Children 12 years and under will usually be given Midazolam Injection into a vein. When Midazolam Injection is used for premedication (to cause relaxation, calm and drowsiness before an anaesthetic) it may be given into the back passage (rectum).

If you are given more Midazolam Injection than you should be

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

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If you are accidentally given too much Midazolam Injection you may:

- Feel drowsy.
- Lose your co-ordination (ataxia) and reflexes.
- Have problems with your speech (dysarthria).
- Have involuntary eye movements (nystagmus).
- Develop low blood pressure (hypotension).
- Stop breathing (apnoea) and suffer cardiorespiratory depression (slowed or stopped breathing and heart beat) and coma.

Stopping treatment with Midazolam Injection

If you receive long term treatment with Midazolam Injection (are given the medicine for a long time) you may:

- Become tolerant to Midazolam Injection. The medicine becomes less effective and does not work as well for you.
- Become dependent upon this medicine and get withdrawal symptoms (see below). Your doctor will reduce your dose gradually to avoid these effects happening to you.

Withdrawal symptoms:

- Benzodiazepine medicines, like Midazolam Injection, may make you dependent. If used for a long time (for instance in intensive care). This means that if you stop treatment suddenly, or lower the dose too quickly, you may get withdrawal symptoms. The symptoms can include:
- headache
- muscle pain
- feeling very worried (anxious), tense, restless, confused or bad-tempered (irritable)
- problems with sleeping (insomnia)
- mood changes
- hallucinations (seeing and possibly hearing things that are not there)
- fits (convulsions).

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Midazolam Injection can cause side effects, although not everybody gets them.

The following undesirable effects have been reported (frequency not known).

Stop having Midazolam Injection and see a doctor straight away if you notice any of the following side effects. They can be life-threatening and you may need urgent medical treatment:

- Anaphylactic shock (a life-threatening allergic reaction). Signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body. You may also have shortness of breath, wheezing or trouble breathing, or a pale skin, a weak and rapid pulse, or feeling of loss of consciousness.
- Heart attack (cardiac arrest). Signs may include tightness of the chest or chest pain which may spread to your neck and shoulders and down your left arm.
- Breathing problems or complications (sometimes causing the breathing to stop).
- Choking and sudden blockage of the airway (laryngospasm).

Life-threatening side effects are more likely to occur in adults over 60 years of age and those who already have breathing difficulties or heart problems, particularly if the injection is given too fast or at a high dose.

Other possible side effects

Not known: frequency cannot be estimated from the available data

- general allergic reactions (skin reactions, heart and blood system reactions, wheezing).
- restlessness, agitation, irritability.
- nervousness, anxiety.
- hostility, anger or aggression.
- excitement.
- hyperactivity.
- changes in libido.
- inappropriate behaviour.
- muscle spasms and muscle tremors (shaking of your muscles that you cannot control).
- confusion, disorientation.
- emotional and mood disturbances.
- involuntary movements.
- nightmares, abnormal dreams.
- hallucinations (seeing and possibly hearing things that are not really there).
- psychoses (losing contact with reality).
- drowsiness and prolonged sedation.
- reduced alertness.
- headache.
- dizziness.
- difficulty co-ordinating muscles.
- fits (convulsions) in premature infants and new-born babies.
- temporary memory loss. How long this last depends on how much Midazolam Injection you were given. You may experience this after your treatment. In isolated cases this has been prolonged (lasted for a long time).
- drug dependence, abuse.
- low blood pressure.
- slow heart rate.
- redness of the face and neck (flushing), feeling faint.
- shortness of breath.
- hiccup.
- feeling sick or being sick.
- constipation.
- dry mouth.
- rash.
- hives (lumpy rash).
- itchiness.
- redness
- swelling of the skin.
- blood clots or pain at the injection site.
- patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).
- tiredness (fatigue).
- patients with severe kidney disease are more likely to experience side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Midazolam Injection

Your doctor or pharmacist is responsible for storing Midazolam Injection. They are also responsible for disposing of any unused Midazolam Injection correctly.

Keep out of the sight and reach of children. You should not be given Midazolam Injection after the expiry date which is printed on the carton and vial label. The doctor, nurse or anaesthetist will check that the expiry date on the label has not been passed before administering the injection to you. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the container in the outer carton in order to protect from light.

6. Contents of the pack and other information

What Midazolam Injection contains

The active substance is Midazolam Hydrochloride 50mg in 50ml. The other ingredients are hydrochloric acid 10%, sodium chloride, sodium hydroxide and water for injections

What Midazolam Injection looks like and contents of the pack

Midazolam Injection is a clear, colourless solution supplied in a clear glass vial containing 50ml of the solution.

Marketing Authorisation Holder

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