Package leaflet: Information for the patient

Midazolam 1 mg/ml solution for injection/infusion

Midazolam 5 mg/ml solution for injection/infusion

midazolam

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 pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Midazolam is and what it is used for

Midazolam contains midazolam. This belongs to a group of medicines called 'benzodiazepines'.
It works quickly to make you feel sleepy or to put you to sleep. It also makes you calm and relaxes your muscles.

Midazolam is used in adults:
- As a general anaesthetic to put you to sleep or to keep you asleep.

It is also used in adults and in children:
- To make you feel calm and sleepy if you are in intensive care. This is called 'sedation'.
- Before and during a medical test or procedure where you are going to stay awake. It makes you feel calm and sleepy. This is called 'conscious sedation'.
- To make you feel calm and sleepy before you are given an anaesthetic.

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

You must not be given Midazolam
- If you are allergic to midazolam or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other benzodiazepine medicines, such as diazepam or nitrazepam.
- If you have severe breathing problems and you are going to receive Midazolam for 'conscious sedation'.

You must not be given Midazolam 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
Your medical history can affect the way in which you are given Midazolam. Check with your doctor or nurse before you are given Midazolam 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 have an illness that makes you feel very weak, run down and short of energy.
- You have something called 'myasthenia gravis' where your muscles are weak.
- You have sleep apnoea (your breathing stops and starts while you sleep).
- You have ever had alcohol problems.
- You have ever had drug problems.

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

Children
Midazolam can be used in children.
If your child is going to be given this medicine:
- Talk to your doctor or nurse if any of the above applies to your child.
- In particular, tell your doctor or nurse if your child has heart or breathing problems.

Other medicines and Midazolam
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This will help your doctor determine the right dose of Midazolam for you.

The following medicines may influence the effect of Midazolam:
- Medicines for depression.
- Hypnotic medicines (to help you sleep).
- Sedatives (to make you feel calm or sleepy).
- Tranquilliser medicines (for anxiety or to help you sleep).
- Carbamazepine or phenytoin (these may be used for fits or seizures).
- Rifampicin (for tuberculosis).
- Medicines for HIV called 'protease inhibitors' (such as saquinavir).
- Antibiotics called 'macrolides' (such as erythromycin or clarithromycin).
- Medicines to treat fungal infections (such as ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole).
- Strong pain killers.
- Atorvastatin (for high cholesterol).
- Anti-histamines (for allergic reactions).
- St John's Wort (a herbal medicine for depression).
- Medicines for high blood pressure called 'calcium channel blockers' (such as diltiazem).

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

Midazolam with drink and alcohol
Do not drink alcohol if you have been given Midazolam. This is because it may make you feel very sleepy and cause problems with your breathing.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.
Your doctor will decide if this medicine is suitable for you.

After you have been given Midazolam do not breast-feed for 24 hours. This is because Midazolam may pass into your breast milk.

Driving and using machines
After receiving Midazolam do not drive or use tools or machines until your doctor says you can.
This is because this medicine may make you feel sleepy or forgetful. It may also affect your concentration and co-ordination. This may affect you being able to drive or use tools and machines.

After your treatment, you must be taken home by an adult who can look after you.

Midazolam contains sodium
Midazolam 1 mg/ml solution for injection/infusion
Midazolam 5 mg/ml solution for injection/infusion
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium free'.
Midazolam 5 mg/ml solution for injection/infusion
1 ml, 2 ml, 3 ml ampoules:
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium free'.

10 ml ampoules:
This medicine contains 28.3 mg sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Midazolam is given

Midazolam will be given to you by a doctor or nurse. It will be given to you in a place that has the equipment needed to monitor you and to treat any side effects. This might be a hospital, clinic or doctor's surgery. In particular, your breathing, heart and circulation will be monitored.

Midazolam is not recommended for use in infants and babies under 6 months of age. However, if the doctor considers it necessary, it can be given to a young child or baby under 6 months in intensive care unit.

How Midazolam is given
You will be given Midazolam in one of the following 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)

How much Midazolam is given
The dose of this medicine varies from one patient to another. The doctor will work out how much to give you. It depends on your age, weight and general health. It also depends on what you need the medicine for, how you respond to treatment, and whether you are going to be given other medicines at the same time.

After being given Midazolam
After your treatment, you must be taken home by an adult who is able to look after you. This is because Midazolam may make you sleepy or forgetful. It may also affect your concentration and co-ordination.
When Midazolam is given for a long time, such as in an intensive care unit, your body can get used to the medicine. This may mean that it may be less effective (see "Long-term use of Midazolam for sedation in intensive care").

If you are given more Midazolam than you should
Since this medicine is administered to you by a trained healthcare professional, it is unlikely that you will be given too much of this medicine. However, if you are given too much by mistake, you may notice the following:
- Feeling sleepy and losing your co-ordination and reflexes.
- Problems with speaking and unusual eye movements.
- Low blood pressure. This may make you feel dizzy or light-headed.
- Slowing or stopping of your breathing or heartbeat and being unconscious (coma).

Long term use of Midazolam for sedation in intensive care
If you are given Midazolam for a long time, the following may happen:
- It may start to work less well.
- You may become dependent on the medicine and get withdrawal symptoms when you stop having it (see "If you stop receiving Midazolam" below).

If you stop receiving Midazolam
If you are given Midazolam for a long time, such as in intensive care, you may get withdrawal symptoms when you stop being given the medicine. These include:
- Mood changes.
- Fits (convulsions).
- Headache.
- Muscle pain.
- Problems with sleeping (insomnia).
- Feeling very worried (anxious), tense, restless, confused or bad tempered (irritable).
- Seeing and possibly hearing things that are not really there (hallucinations).

Your doctor will lower your dose gradually. This will help to stop withdrawal symptoms from happening to you.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine. The following side effects have been reported (frequency not known, cannot be estimated from the available data).

Stop receiving Midazolam 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:
- A severe allergic reaction (anaphylactic shock). The signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body (angioedema).
- 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. Additionally, you may experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Heart attack (cardiac arrest). The signs may include chest pain.
- Breathing problems, sometimes causing the breathing to stop.
- Choking and sudden blockage of the airway (laryngospasm).

Life-threatening side effects are more likely in adults over 60 years, and in people who already have breathing or heart problems. These side effects are also more likely if the injection is given too fast or at a high dose.

Other possible side effects:

Nervous system and mental disorders
- Being less alert.
- Feeling confused.
- Feeling very happy or excited (euphoria).
- Changes in sexual drive.
- Feeling tired or sleepy or being sedated for a long time.
- Seeing or possibly hearing things that are not really there (hallucinations).
- Headache.
- Feeling dizzy.
- Difficulty co-ordinating muscles.
- Fits (convulsions) in premature and new-born babies.
- Temporary memory loss. How long this lasts depends on how much Midazolam you were given. Occasionally this has lasted for a long time.
- Feeling agitated, restless, angry or aggressive. You may also have muscle spasms or shaking of your muscles that you cannot control (tremors). These effects are more likely if you have been given a high dose of Midazolam or if it has been given too quickly. It is also more likely in children and elderly people.

Contact your doctor if you notice that you are becoming dependent on this medicine or if you notice that you become insensitive to the effects and therefore need to increase the dose.

Heart and blood vessel disorders
- Fainting.
- Slow heart rate.
- Redness of the face and neck (flushing).
- Low blood pressure. This may make you feel dizzy or light-headed.

Respiratory disorders
- Hiccups.
- Being short of breath.

Gastrointestinal (stomach and intestines) disorders
- Dry mouth.
- Constipation.
- Feeling sick (nausea) or being sick (vomiting).

Skin and subcutaneous tissue disorders
- Feeling itchy.
- Rash, including a lumpy rash (hives).

- Redness, pain, blood clots or swelling of the skin where the injection was given.

General
- Allergic reactions including skin rash and wheezing.
- Withdrawal symptoms (see 'If you stop receiving Midazolam' in Section 3 above).
- Falling and breaking bones. The risk is increased if you take other medicines at the same time which are known to cause drowsiness (for example calming or sleeping medicines), or alcohol **.**

Elderly people
- Older people taking benzodiazepine medicines, like Midazolam have a higher risk of falling and breaking bones.
- Life-threatening side effects are also more likely to happen in adults over 60 years.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Midazolam

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Keep the ampoule in the outer carton in order to protect from light.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C and or for 3 days at 2 to 8°C with sodium chloride 9 mg/mL (0.9%), glucose 50 mg/ml (5%) or 100 mg/ml (10%), fructose 50 mg/ml (5%), Ringer's solution or Hartmann's solution.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

This medicine must not be used if there are visible signs of deterioration.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Midazolam contains
- The active substance is midazolam.

Midazolam 1 mg/ml solution for injection/infusion
Each ml of solution for injection/infusion contains 1 mg of midazolam.
Each ampoule of 5 ml contains 5 mg of midazolam.

Midazolam 5 mg/ml solution for injection/infusion
Each ml of solution for injection/infusion contains 5 mg of midazolam.
Each ampoule of 1 ml contains 5 mg of midazolam.
Each ampoule of 2 ml contains 10 mg of midazolam.

Each ampoule of 3 ml contains 15 mg of midazolam.
Each ampoule of 10 ml contains 50 mg of midazolam.

- The other ingredients are sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid, concentrated (for pH adjustment), and water for injections.

What Midazolam looks like and contents of the pack

Midazolam 1 mg/ml solution for injection/infusion

Midazolam is a clear colourless solution for injection/infusion in a 5 ml glass ampoules. Each pack contains 10 or 50 ampoules.

Midazolam 5 mg/ml solution for injection/infusion
Midazolam is a clear colourless solution for injection/infusion in a 1 ml, 2 ml, 3 ml or 10 ml glass ampoules. Each pack contains 10 or 50 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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France

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