



MercuryPharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Midazolam 2mg/ml Solution for Injection/Infusion
Midazolam 5mg/ml Solution for Injection/Infusion

Read all of this leaflet carefully before you start using 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.

The name of your medicine is Midazolam 2mg/ml Solution for Injection/Infusion, Midazolam 5mg/ml Solution for Injection/Infusion; it will be called Midazolam Injection for ease here after.

What is in this leaflet:

1. What Midazolam Injection is and what it is used for
2. What you need to know before you use Midazolam
3. How to use Midazolam
4. Possible side effects
5. How to store Midazolam
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 called benzodiazepines. It can cause you to fall asleep and it can also relieve anxiety, relax muscles and prevent convulsions.

Midazolam is used to:

- Sedate patients before and during minor medical, dental and surgical procedures (such as passing a tube into the stomach, intestine, bladder, lungs or heart)
- Provide sedation for patients in intensive care
- Bring about anaesthesia in high risk and elderly patients, especially where it is important to keep the heart and blood vessels in a stable state. This works best when heavy opiate (narcotic) premedication has been given, or when midazolam is given with a narcotic pain relieving drug such as fentanyl.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MIDAZOLAM

Do not use Midazolam Injection if:

- You know that you are allergic to Midazolam or any other benzodiazepines, or to any of the other ingredients of this medicine (listed in section 6)
- You have severe breathing problems and you are going to have Midazolam Injection for conscious sedation.

Speak to your doctor if this applies to you **before** you are given Midazolam Injection.

Warnings and precautions

Talk to your doctor or nurse before using Midazolam Injection.

Children and babies

If your child is going to be given this medicine:

It is very important to tell your doctor or nurse if your child has cardiovascular disease (heart problems). Your child will be 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 know if:

- You suffer from a lung or breathing disorder
- You have a problem with your kidneys or liver
- You are over 60 years old and or have recently been poorly
- You are debilitated (have an illness that makes you feel very weak, run down and short of energy)
- You regularly drink large amounts of alcohol or you have had problems with alcohol use in the past
- You regularly take recreational drugs or you have had a problem with drug use in the past
- You are pregnant or think you may be pregnant (see 'Pregnancy and breast-feeding')
- You suffer from a condition called myasthenia gravis (which causes severe weakness of the muscles)
- You have a personality disorder
- You suffer from heart disease or have abnormally low volume of blood in the circulation (for example, due to heavy and abnormal bleeding, dehydration or severe burns).

Tell your doctor if any of these apply to you **before** you are given this medicine.

Other medicines and Midazolam Injection

Tell your doctor or nurse if you are taking, have recently taken used or might take any other medicines.

In particular, tell your doctor if you are taking any of the following:

- Drugs that act on the brain and spinal cord (such as strong pain relievers)
- Diltiazem or verapamil (for angina or hypertension; verapamil may also be used to control irregular heartbeats)
- Fluconazole, ketoconazole, voriconazole, posaconazole or itraconazole (anti-fungal medicines)
- Erythromycin or clarithromycin (antibiotics)
- Saquinavir (used to treat HIV infections and AIDS) and similar medicines called Protease Inhibitors
- Any other benzodiazepine drug, hypnotic, sedative or tranquiliser (for anxiety or to help you sleep)
- Antidepressants (medicines to treat depression)
- Antihistamine (used to treat allergies)
- Atorvastatin (used to treat high cholesterol)
- Rifampicin (used to treat mycobacterial infections such as tuberculosis)
- St John's Wort (a herb).

If you are already taking one of these medicines, speak to your doctor **before** you are given Midazolam Injection.

Midazolam Injection with food, drink and alcohol

You should avoid drinking alcohol for at least 8 hours before and after being given Midazolam Injection. This is because alcohol can increase the sedative effect of Midazolam Injection and can cause problems with your breathing.

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.

Pregnancy, breast-feeding and fertility

Tell your doctor **before** you are given this medicine if you are or think you may be pregnant or are planning to become pregnant or are breastfeeding.

As midazolam may be found in breast milk you should not breast-feed for 24 hours after being given Midazolam Injection.

Ask your doctor or pharmacist for advice **before** taking any medicine.

Driving and using machines:

- Do not drive or operate machinery for at least 12 hours after you receive Midazolam Injection alone for intravenous sedation prior to a minor procedure
- If Midazolam Injection is used along with other drugs that can affect the brain or spinal cord (such as strong pain relievers), you may take longer to recover from the combined effects; in this case, you should ask your doctor for advice about when you may return home or resume normal activities. Midazolam Injection may make you sleepy, forgetful or affect your concentration and co-ordination. This may affect your performance at skilled tasks such as driving or using machinery.

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

Midazolam Injection contains Sodium

Midazolam 10 mg/5 ml Solution for Injection or Infusion contains 3.542mg sodium in 1 ml. This means that it is essentially sodium free unless the dose is more than 6.5 ml at a time and Midazolam 10mg/2ml Solution for Injection or Infusion contains 1.96mg sodium in 1 ml. This means that it is essentially sodium free unless the dose is more than 11.7 ml at a time.

Discuss this with your doctor if you are on a controlled sodium diet.



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Version No: 100476/LF/021/02
100478/LF/021/02
Product Name: Midazolam 2 mg/ml Sol for Inj/Inf
Midazolam 5 mg/ml Sol for Inj/Inf
Pack Size: 10 Ampoules
Component: Leaflet
SKU: 100476 / 100478
Market: Ireland
Production Site: B Braun
Revision No.: 1
Revision Date: 02/12/2014
Revised by: ADD

Dimension: 420 x 148 mm
Commodity No.: N/A
Pharma Code: N/A
Core Spec Ref: N/A
DCMF: N/A
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Non-Print Colours: Cutter

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3. HOW TO USE MIDAZOLAM INJECTION

Midazolam Injection will be given only by experienced doctors and trained people in a setting fully equipped for life support and who will recognize and be able to treat known side effects if they happen. Midazolam Injection may be given by intravenous injection (injection into a vein) or by intravenous infusion (given by a drip into the vein). Your doctor will decide on the dose to be given based on your particular procedure that they will be doing, the degree of sleep (sedation) required, your weight and your response to this medicine. If you think you have been given more Midazolam Injection than you should have This is unlikely as your injection will be administered by a doctor or nurse. If you are concerned about the dose, discuss this with your doctor. If you have any further questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Midazolam Injection can cause side-effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are very rare. Stop taking Midazolam Injection and see a doctor straight away if you notice any of the following side effects:

- Any sudden wheeziness, difficulty in breathing, swelling of the eye lids, face or lips, rash or itching (especially of your whole body) this is called Anaphylactic shock and is life- threatening
- Heart attack (cardiac arrest). Signs may include 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. The following side effects have also been reported:

Immune system problems:

- General allergic reactions (skin reactions, heart and blood system reactions, wheezing).

Effects on behavior:

- Agitation
- Hostility, rage or aggression
- Potential drug dependence and withdrawal syndrome
- Restlessness
- Excitement
- Abuse of Midazolam.

Muscle problems:

- Muscle spasms and muscle tremors (shaking of your muscles that you cannot control).

Mental and Nervous system problems:

- Confusion
- Euphoria (an excessive feeling of happiness or excitement)
- Hallucinations (seeing and possibly hearing things that are not really there)
- 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 lasts 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).

Heart and circulation problems:

- Low blood pressure
- Redness of the face and neck (flushing), fainting or headache.
- Slow heart rate

Breathing problems:

- Shortness of breath
- Hiccup.

Stomach, gut and mouth problems:

- Feeling sick or being sick
- Dry mouth.
- Constipation

Skin problems:

- Rash
- Itchiness.
- Hives (lumpy rash)

Injection site problems:

- Redness
- Blood clots or pain at the injection site.
- Swelling of the skin

General:

- Tiredness (fatigue).

Elderly patients:

- Older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones
- 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 when the injection is given too quickly or at a high dose.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MIDAZOLAM INJECTION

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 label after 'Exp'. The expiry date refers to the last day of that month. Keep the ampoule in the outer carton in order to protect from light. Do not store above 25°C. For single use only. Once the ampoule has been opened it should be used immediately. If only part used, discard the remaining solution. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Midazolam Injection contains The active substance is Midazolam. Midazolam 5mg/ml: Each 2ml ampoule contains 10mg of midazolam. Midazolam 2mg/ml: Each 5ml ampoule contains 10mg of midazolam. The other ingredients are sodium chloride, hydrochloric acid and sodium hydroxide in water for injections. What Midazolam Injection looks like and contents of pack Midazolam 2mg/ml Solution for Injection/Infusion is a clear, colourless or slightly yellow, sterile solution for injection or infusion. Each 5ml glass ampoule contains 10mg of active ingredient, Midazolam. Midazolam 5mg/ml Solution for Injection/Infusion is a clear, colourless or slightly yellow, sterile solution for injection or infusion. Each 2ml glass ampoule contains 10mg of active ingredient, Midazolam. Pack size: 5 or 10 ampoules may be packaged together in cartons. Not all pack sizes may be marketed. Marketing Authorisation Holder Mercury Pharmaceuticals (Ireland) Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland Manufacturer B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany This leaflet was last revised in December 2014.

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