MIDAZOLAM 2mg/ml Solution for Injection/Infusion

1. WHAT MIDAZOLAM INJECTION IS AND WHAT IT IS USED FOR

Midazolam injection contains midazolam. Midazolam belongs to a group of medicines called benzodiazepines which can cause sedation (sleepiness) or mild anxiety.

It is used:
- to sedate patients during minor surgical and dental operations, and medical procedures such as passing a tube into the stomach or bladder both in children and adult
- to sedate patients in intensive care
- as an anaesthetic in high risk and elderly patients
- by injection into a muscle to provide pre-medication for some patients prior to surgery

2. 2. YOU NEED TO KNOW BEFORE YOU ARE GIVEN MIDAZOLAM INJECTION

You must not be given Midazolam Injection if:
- you are allergic to midazolam or any other benzodiazepines or to any of the other ingredients of this medicine (listed in section 4).
- you have severe breathing problems and you are going to have Midazolam Injection for conscious sedation.
- you have not been 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
Talk to your doctor or nurse before you are given Midazolam Injection if:
- you are over 60 years of age
- you have severe breathing problems or a history of breathing disorders
- you have a problem with your kidneys or liver
- you are over 60 years of age
- you have severe breathing problems and you are going to have Midazolam Injection for conscious sedation.

For 25ml: This medicinal product contains 88.5mg sodium (main component of cooking/table salt) in each 25ml

For 5ml: This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. POSSIBLE SIDE EFFECTS

You may experience:
- dry mouth
- headache
- dizziness or fainting
- confusion
- euphoria (an excessive feeling of happiness or excitement)
- temporary memory loss - how long this occurs and excitement particularly in children and older patients
- not recognised (frequency cannot be estimated from the available data):


- allergic reactions (including anaphylaxis and angioedema - a swollen face, lips, tongue or other parts of the body) and breathing difficulties
- breathlessness
- chest pain
- changes in your vision
- convulsions
- decreased urine output
- difficult or laboured breathing
- difficulty swallowing
- injury or bleeding
- inflammation of veins, clotting in blood vessels
- feeling of sick or being sick
- increased bleeding tendencies
- increased heart rate
- palpitations
- seizures
- swelling
- tremors

4. POSSIBLE SIDE EFFECTS

Midazolam Injection may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if you are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.

5. INSTRUCTIONS ON HOW TO USE MIDAZOLAM INJECTION

- Midazolam Injection is given by injection into a vein. When Midazolam Injection is used
- by injecting into a muscle (intramuscular injection),
- by a drip into a vein).

- you are pregnant or think you may be pregnant (see "Pregnancy and breast-feeding"
- you have a problem with your kidneys or liver
- you are over 60 years of age
- severe breathing problems and you are going to have Midazolam Injection for conscious sedation.

For 25ml: This medicinal product contains 88.5mg sodium (main component of cooking/table salt) in each 25ml

For 5ml: This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".
You are taking any medicine from the group of medicines known as opioids: taking these medicines with Midazolam may cause problems with your breathing.

If you suffer from heart disease and have abnormally low volume of blood in circulation (for example due to bleeding, dehydration, loss had been prolonged (lasted for a long time) • potential drug dependence and withdrawal syndrome • hives (lumpy rash)

Older patients:

Other medicines and Midazolam Injection:

Other possible side effects:
The following side effects have been reported since the marketing of midazolam injection:

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You should report any adverse drug reactions on a yellow card or at www.mhra.gov.uk/yellowcard.

Reporting of side effects

If you have any further questions, ask your doctor or pharmacist.

What is Midazolam Injection?

Midazolam Injection contains:

The active substance in midazolam contains:

The other ingredients are sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

What Midazolam Injection looks like and contents of pack

Midazolam hydrochloride 2mg in the exit dose: colourless or slightly yellow, sterile solution contained in clear glass ampoules

The product is available in packs of 5 and 10mls.

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.

It is an offence to drive if this medicine affects your ability to drive

This product will be referred to as Midazolam Injection from here on.

This may affect your performance at skilled tasks such as driving or using machines.

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

Advice before taking this medicine.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby ask your doctor for advice before taking this medicine.

Use in Children

In infancy 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 anesthetic) it may be given into the back passage (rectum).

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

Take to your doctor or nurse if you are not sure whether it is safe for you to drive after receiving this medicine.

Midazolam Injection may be administered by intravenous injection into a vein or by intravenous infusion (given slowly over a period of time).

Your doctor will decide on the dose to be given based on the particular procedure they are doing, the degree of sleep (sedation) required, your weight your response to the medication.

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

• by direct injection into a vein (intravenous injection);
• through a tube into one of your veins (intravenous infusion);
• by injecting into a muscle (intramuscular injection);
• into the back passage (rectum).

Talk to your doctor or nurse before you are given Midazolam Injection if:

• to sedate patients in intensive care;
• for surgical procedures;
• for patients with severe psychiatric disorders;
• to aid sleep;
• to relax muscles;
• to make you feel less anxious;
• to make you feel less painful;
• to help you with your breathing;
• to help you to pass away (rectum);
• to stop shaking (tremor) or to stop muscle spasms;
• to help you when you have had a stroke;
• to help you when you have had a heart attack;
• to help you when you have had an operation;
• to help you when you have had an accident;
• to help you when you have had a spill;
• to help you when you have had a fall;
• to help you when you have had a cut;
• to help you when you have had a burn;
• to help you when you have had a bruise;
• to help you when you have had a wound;
• to help you when you have had a rash;
• to help you when you have had a rash;