5. How to store Midazolam Injection

This medicine should not be given to anyone who is allergic to any of its ingredients or has had an allergic reaction in the past.

6. Warning and precautions

Midazolam Injection is given to your doctor or nurse.

If you are over 60 years of age.

You may have a higher risk of falling and breaking bones.

If you have any side effects, you should talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

The following undesirable effects have been reported with Midazolam Injection:

• Rash
• Swelling of the face, lips, tongue or other parts of the body. You should stop treatment immediately and call your doctor or nurse.
• Dizziness, sickness or feeling sick
• Headache
• Feel drowsy
• Feel tired (fatigue)
• Feel forgetful or affect your concentration and ability to learn
• Changes in the way you think, feel or behave
• Feel anxious or have nightmares
• Feel shaky, nervous or have palpitations
• Feel confused
• Feel slowed down
• Develop low blood pressure (hypotension).
• Have involuntary eye movements (nystagmus).
• Have problems with your speech (dysarthria).
• Lose your co-ordination (ataxia) and reflexes.
• Feel drowsy.
• Have sweating that is not related to exercise.
• Sudden reduction in vision.
• Breathing difficulties.
• Anaphylactic shock (a life-threatening allergic reaction).
• Low blood pressure.

Do not use this medicine after the expiry date listed on the pack. If you do, it may not work as well for you.

Anyhow, your state of health, how you respond to Midazolam Injection and whether other medicines are needed is the same as the dose that you can use without risk.

The other ingredients in both strengths are:

• Sodium chloride 9%
• Hydrochloric acid
• Sodium hydroxide as required to adjust the pH.
• Sodium metabisulphite (as sodium bisulphite or sodium hydrogen bisulphite)
• Inactive ingredients such as lactose.

Midazolam Solution for Injection or Infusion is a clear, colourless or slightly yellow solution.

Midazolam Injection is used for premedication given Midazolam Injection into a vein. When given Midazolam Injection is used to cause a state of calm or drowsiness during a medical procedure or in an emergency. If you are not sure whether it is safe for you to drive while you are using this medicine, you should ask your doctor or nurse for advice before taking this medicine.

Do not drive for 24 hours after being given Midazolam Injection. The effects of Midazolam Injection may pass into your bloodstream.

To ensure that the product is not discoloured.

The following information is intended for medical or healthcare professionals only.

Midazolam 5 mg/ml Solution for Injection or Infusion is a clear, colourless or slightly yellow solution.

Midazolam Injection is used for premedication given Midazolam Injection into a vein. When given Midazolam Injection is used to cause a state of calm or drowsiness during a medical procedure or in an emergency.

The following undesirable effects have been reported with Midazolam Injection:

• Rash
• Swelling of the face, lips, tongue or other parts of the body. You should stop treatment immediately and call your doctor or nurse.
• Dizziness, sickness or feeling sick
• Headache
• Feel drowsy
• Feel tired (fatigue)
• Feel forgetful or affect your concentration and ability to learn
• Changes in the way you think, feel or behave
• Feel anxious or have nightmares
• Feel shaky, nervous or have palpitations
• Feel confused
• Feel slowed down
• Develop low blood pressure (hypotension).
• Have involuntary eye movements (nystagmus).
• Have problems with your speech (dysarthria).
• Lose your co-ordination (ataxia) and reflexes.
• Feel drowsy.
• Have sweating that is not related to exercise.
• Sudden reduction in vision.
• Breathing difficulties.
• Anaphylactic shock (a life-threatening allergic reaction).
• Low blood pressure.

Do not use this medicine after the expiry date listed on the pack. If you do, it may not work as well for you.

Anyhow, your state of health, how you respond to Midazolam Injection and whether other medicines are needed is the same as the dose that you can use without risk.

The other ingredients in both strengths are:

• Sodium chloride 9%
• Hydrochloric acid
• Sodium hydroxide as required to adjust the pH.
• Sodium metabisulphite (as sodium bisulphite or sodium hydrogen bisulphite)
• Inactive ingredients such as lactose.

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• Lose your co-ordination (ataxia) and reflexes.
• Feel drowsy.
• Have sweating that is not related to exercise.
• Sudden reduction in vision.
• Breathing difficulties.
• Anaphylactic shock (a life-threatening allergic reaction).
• Low blood pressure.

Do not use this medicine after the expiry date listed on the pack. If you do, it may not work as well for you.

Anyhow, your state of health, how you respond to Midazolam Injection and whether other medicines are needed is the same as the dose that you can use without risk.
Midazolam 5 mg/ml Solution for Injection or Infusion is available in 5 ml Type I glass ampoules. Midazolam 2 mg/ml Solution for Injection or Infusion is available in 5 ml Type I glass ampoules. It is sterile and contains no additional stabilizers. The solution also contains the inactive ingredients sodium chloride, hydrochloric acid, sodium hydroxide and water for injections. Each ampoule contains 5 mg of midazolam (as midazolam hydrochloride). The active substance in the injection is midazolam (5 mg/ml).

6. How to store Midazolam Injection

1. If you receive more Midazolam Injection than you were prescribed - be careful when you take your medicine. If you accidentally give someone else this medicine (midazolam injection or infusion) they may:• feel drowsy,• have trouble in concentrating (especially in children). This may affect how safe and effective the medicine and any other medicines you are taking are (see below) (see below). Your doctor or nurse will normally give you the right dose to help you get well, but this may affect how safe and effective the medicine and any other medicines you are taking are (see below).

2. Keep this leaflet. You may need to read it again.

3. How to store Midazolam Injection

4. Possible side effects

5. How to store Midazolam Injection

6. Contents of the pack and storage

7. Possible side effects

8. What Midazolam Injection contains

9. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, then talk to your doctor or nurse before starting this medicine. You may need new or additional medicines for HIV called protease inhibitors, clarithromycin, itraconazole, posaconazole, diltiazem (used to treat high blood pressure), methadone and other narcotic analgesics (very strong pain killers) in the way described above. Midazolam Injection may make you sleepy, confused or bad-tempered (irritable) which increases the risk of your falling and breaking bones. Your doctor or pharmacist is responsible for ensuring that the medicine is made, packaged and given to you in a way that will help you to get well and will make you safe to drive. Do not drink alcohol if you have been given Midazolam Injection, including any that comes into your back passage (rectum). This leaflet was last revised in April 2014.