You should always be taken home by a responsible adult after your treatment, if you have received midazolam injection. 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, if you have received midazolam injection.

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.

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

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 injection
3. How to use Midazolam injection
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 called benzodiazepines which can cause sedation (sleepiness) and relieve anxiety.

- to sedate patients during minor surgical and dental operations, and medical procedures such as passing a tube into the stomach or bladder
- to sedate patients in intensive care unit
- as an anaesthetic in high risk and elderly patients
- by injection into a muscle to provide pre medication for some patients prior to surgery.
- to sedate patients during minor surgical and dental operations, and medical procedures such as passing a tube into the stomach or bladder
- to sedate patients in intensive care unit
- 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. What you need to know before you use Midazolam injection

Do not use Midazolam Injection if you are allergic to Midazolam (or any other similar benzodiazepines) or to any of the other ingredients of this medicine (listed in section 6).

Speak to your doctor if this applies to you before you are given this medicine.

Children and babies:

- If your child is going to be given this medicine:
  - if you suffer from a lung or breathing disorder
  - if you are debilitated (have an illness that makes you feel very weak, run down and short of energy)
  - if you are already taking one of these medicines, speak to your doctor before you receive Midazolam Injection.

Warnings and precautions:

- Talk to your doctor or pharmacist before using Midazolam injection if:
  - you are over 60 years of age
  - you are over 60 years of age
  - you are under the age of 12 years old
  - you have problems with your kidneys or liver
  - you have problems with your kidneys or liver
  - you cannot swallow or take medicine by mouth
  - you are pregnant or think you may be pregnant
  - you are pregnant or think you may be pregnant
  - you are breast feeding
  - you are breast feeding

Other medicines and Midazolam Injection:

Tell your doctor or nurse if you are taking, have recently taken used or might take any other medicines. This is important to tell your doctor or nurse if you are taking any of the following:

- strong pain relievers, such as codeine or pethidine
- strong pain relievers, such as codeine or pethidine
- as an anaesthetic in high risk and elderly patients
- by injection into a muscle to provide pre medication for some patients prior to surgery.

Driving and using machines:

- Midazolam Injection will affect your ability to drive and operate machinery. You should speak to your doctor for advice on when you will be able to drive, operate machines 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 machines.
- Midazolam Injection will affect your ability to drive and operate machinery. You should speak to your doctor for advice on when you will be able to drive, operate machines 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 machines.
The medicine can affect your ability to drive as it may make you sleepy or dizzy.  
- do not drive while taking this medicine until you know how it affects you 
- 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 been told 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.

Midazolam Injection contains Sodium

This medicinal product contains 3.44 mg sodium in 1ml. This means that it is essentially sodium free unless the dose exceeds 6.8 ml at a time. Discuss this with your doctor if you are on a controlled sodium diet.

1. HOW TO USE MIDAZOLAM INJECTION

Midazolam Injection may be administered by intravenous injection (injection into a vein) or by intravenous infusion (given by a drip into a vein).

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 and your response to the medication. Severe problems with heart and breathing are most likely to occur when the injection is given too rapidly or when too high a dose is used.

If you think you have been given more Midazolam injection than you should have,  
- it was not affecting your ability to drive safely.
- you would not be committing an offence if:  
- the medicine has been prescribed to treat a medical or dental problem and 
- you have been told 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.

Withdrawal symptoms:

Benzodiazepines, like midazolam injection, may make you dependent if used for a long time. 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 product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side-effects, although not everyone gets them. See how midazolam injection and see your 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 (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 have shortness of breath, wheezing or troubled breathing.
- 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). 
- chocking 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:
The following side effects have been reported since the marketing of midazolam but the frequency for them to occur is not known (frequency cannot be estimated from the available data):

- confusion
- euphoria
- anxiety
- hallucinations (seeing and possibly hearing things that are not really there)
- drowsiness and prolongated sedation
- dizziness
- nausea
- diarrhoea
- palpitations
- numbness
- blood pressure drop
- increased heart rate
- drug-induced fever
- weight loss
- fits (convulsion) due to withdrawal of drug
- temporary memory loss - how long this occurs depends on how much midazolam was given to you. You may experience this temporary memory loss after your treatment. In isolated cases temporary memory loss had been prolonged (lasted for a long time)
- agitation, restlessness, hostility, rage or aggression and excitement particularly in children and older patients
- potential drug dependence and withdrawal syndrome

Order people:
- older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones

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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MIDAZOLAM INJECTION

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 ampoules (small bottles) in the outer carton in order to protect from light.

Do not store above 25°C.

Do not use the ampoule if it is damaged or the contents are discoloured.

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

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

The active substance is midazolam.

What Midazolam Injection looks like and contents of pack:

Midazolam Injection lmg in 1ml is a clear, colourless or slightly yellow, sterile solution contained in clear glass ampoules (small bottles). Each vial of this solution contains 5mg of midazolam.

The injection is available in packs of 10 ampoules containing 2ml or 10ml of solution.

Marketing authorization holder:

Mercury Pharma International Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer:

B. Braun Melsungen AG, Malseweg 2, 12367 Berlin, Germany.

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