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) and relieve 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
• to sedate patients in intensive care units
• as an anaesthetic in high-risk and elderly patients
• to induce sleep in a patient to provide pre medication for some patients prior to surgery

2. WHAT 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 of the other benzodiazepines or to any of the other ingredients of this medicine (listed in section 6).
• you have severe breathing problems and you are having Midazolam injection for conscious sedation.

You must not be given this medicine 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.

Pregnancy and breast-feeding

If you have passed through prolonged treatment during last phase of pregnancy with this medicine, your baby may develop physical dependence and risk of withdrawal symptoms after birth.

Breast-feeding

Do not breast-feed for 24 hours after being given midazolam injection. This is because midazolam may pass into your breast milk.

Driving and using machinery:

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 machinery or resume normal activities.

MIDAZOLAM INJECTION may make you sleepy, forgetful or affect your concentration and coordination. This may affect your performance at skilled tasks such as driving or using machines.

You should always be taken home by a responsible adult after your treatment. If you have received midazolam injection, The medicine can affect your ability to drive as it may make you sleepy or drowsy.
• do not drive after receiving this medicine until you know how it affects you
• it is an offence to drive if this medicine affects your ability to drive

6. CONTENTS OF THE PACK AND OTHER INFORMATION

- the medicines effective against vomiting and nausea, such as nabilone.
- herbal medicine St John’s Wort
- sedatives (medicines that make you feel calm or sleepy)
- hypnotics (medicines that make you sleep)
- the anti-fungal medicines ketoconazole, voriconazole, fluconazole, posaconazole or itraconazole
- medicines known as water pills or diuretics
- diltiazem, nifedipine or verapamil (used for angina or high blood pressure, verapamil may also be used to control irregular heartbeats).

In particular, tell your doctor or nurse if you are taking any of the medicine following:
• opioids are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.
• redness of face and neck (flushing) • inflammation of veins, clotting in blood vessels
• fits (convulsion) due to withdrawal of drug • temporary memory loss — how long this occurs depends
• dizziness or fainting • fits (convulsion) in premature infants and new-born babies
• medicines used in IV infections (caused prostate infections (such as sepsis) and wheezing
• atorvastatin (used to keep high cholesterol levels in blood)
• statins (used to decrease the levels of fats such as cholesterol and triglycerides)
• oral contraceptives used to suppress the menstrual cycle
- medicines used to treat cancer such as chemotherapy
• medicines effective against vomiting and nausea, such as:

If you are already taking one of these medicines, speak to your doctor before you receive Midazolam injection.

If any of the above applies to you, or if you are not sure, talk to your doctor or nurse before you are given this medicine.

Other medicines and Midazolam Injection:

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

If you are already taking one of these medicines, speak to your doctor before you receive Midazolam injection.

If you have passed through prolonged treatment during last phase of pregnancy with this medicine, your baby may develop physical dependence and risk of withdrawal symptoms after birth.

Breast-feeding

Do not breast-feed for 24 hours after being given midazolam injection. This is because midazolam may pass into your breast milk.

Driving and using machinery:

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 machinery or resume normal activities.

MIDAZOLAM INJECTION may make you sleepy, forgetful or affect your concentration and coordination. This may affect your performance at skilled tasks such as driving or using machines.

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PATIENT INFORMATION LEAFLET

Midazolam 5mg/ml Solution for Injection/Infusion

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 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 is 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 are given Midazolam Injection
3. How you will be given Midazolam Injection
4. Possible side effects
5. How to store Midazolam Injection
6. Contents of the pack and other information
do not drive after receiving this medicine until you know how it affects you. The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not breast-feed for 24 hours after being given midazolam injection. This is because midazolam may pass into your breast milk. If you are pregnant or breast-feeding think you may be pregnant or are planning to have a baby ask your doctor for advice. Pregnancy and breast-feeding should be limited by your doctor. Older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones.

- Not known (frequency cannot be estimated from the available data):
  - hallucinations (seeing and possibly hearing things that are not there), speech or thinking problems, agitation, anxiety and restlessness, speak to your doctor or nurse.

- Potentially dangerous side effects that need to be reported immediately:
  - anaphylactic shock (a 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.
  - dry mouth
  - hives (lumpy rash)
  - Hiccup been prolonged (lasted for a long time)
  - feeling of sick or being sick
  - confusion • euphoria (an excessive feeling of happiness or excitement)
  - difficulty in swallowing
  - feeling of tiredness or weakness
  - speech problems (slurred speech), breathing problems, tiredness, cold feet or hands, weakness, cold sweat, muscle weakness
  - blurred vision
  - problems with sleeping (insomnia)
  - mood changes
  - nightmares
  - abnormal dreams
  - want to take more than the usual amount of medicine
  - keeling over
  - fever
  - an intense feeling of hunger
  - skin rashes, skin infections
  - feeling of falling

- Other possible side effects:
  - changes in your thinking or behaviour (including depression or abnormal thoughts or actions)
  - feeling very relaxed or sleepy
  - reduced sexual performance
  - potential drug dependence and withdrawal syndrome
  - low blood pressure
  - difficulty in swallowing
  - feeling of loss of taste
  - feeling of numbness
  - tingling
  - muscle spasms and muscle weakness
  - shaking of muscles that you cannot control
  - Falls and fractures

- Older people:
  - Older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones.
  - Drug dependence, abuse and withdrawal. If you have received Midazolam injection for a long time, you may find yourself becoming addicted and experience withdrawal symptoms once discontinued. If you have symptoms of agitation, anxiety and restlessness, speak to your doctor or nurse.

- Reporting of side effects
  - If you get any side effects, talk to your doctor or this nurse. Include this 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 refer 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.
- Do not throw away any medicines via wastewater or household waste. 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

- Midazolam Injection contains Sodium
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

- Midazolam Injection will be given only by experienced doctors and trained people in a setting fully equipped for life support and who will recognise and be able to treat known side effects if they happen.

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

- In infants 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 as a premedication (to cause relaxation, calm and drowsiness before an anaesthetic); it may be given into the back passage (rectum).

- 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 it with your doctor.

- If you are accidentally given too much midazolam injection you may feel drowsy, lose your co-ordination (altered) and reflexes. Rare problems with your speech (aphasia), have problems with eye movements (nystagmus) develop low blood pressure (hypotension), stop breathing (apnoea) and suffer cardiomyopathy (slowed or stopped breathing and heart beat) and coma.

- If you stop using Midazolam injection:

  - If you are given midazolam injection for a long time you may:
    - become tolerant to it. The medicine becomes less effective and does not work as well for you
    - become dependent upon this medicine and get withdrawal symptoms (see below)

- Your doctor will reduce your dose gradually to avoid these effects happening to you.

- Withdrawal symptoms:

  - Benzodiazepine medicines, 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:
    - tremors (trembling, shaking), inability to move (stiffness), loss of balance,
    - agitation, anxiety and restlessness, auditory and visual hallucinations (hearing and seeing things that are not real)
    - an increase in the amount of urine, diarrhea
    - loss of appetite
    - increased drowsiness
    - nausea
    - an increase in blood pressure
    - nightmares
    - insomnia (problems with sleeping)
    - rashes and blisters
    - convulsions

- In particular, tell your doctor or nurse if you are taking any of the medicine following:

  - medicines effective against vomiting and nausea, such as nabilone.
  - ciclosporin used to suppress the immune system
  - rifampicin (used to treat mycobacterial infections such as tuberculosis)
  - atorvastatin (used to treat high cholesterol levels in blood)
  - medicines used in HIV infections called protease inhibitors (such as saquinavir) and efavirenz
  - sedatives (medicines that make you feel calm or sleepy)

- This is extremely important because some medicines can strengthen or weaken the effects of others.

- If any of the above applies to you, or if you are not sure, talk to your doctor or nurse before you are given this medicine.

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

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