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

- it is an offence to drive if this medicine affects your ability to drive

Midazolam injection may make you sleepy, forgetful or affect your concentration and co-ordination. This may affect your when you will be able to drive, operate machines or resume normal activities.

Driving and using machines:

- if you have had an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

However if your doctor does prescribe Midazolam Injection together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Other medicines and 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.

3. HOW YOU WILL BE GIVEN MIDAZOLAM INJECTION

- if you stop using Midazolam injection:

- if you stop treatment suddenly, or lower the dose too quickly, you may get withdrawal symptoms. The symptoms can

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

If you stop using Midazolam injection:

- if you have symptoms of find yourself becoming addicted and experience withdrawal symptoms once discontinued. If you have symptoms of

Alcohol should be avoided during 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 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.

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 it as may make you drowsy or dizzy.

- do not drive after receiving this medicine until you know how it affects you

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 your breathing.

Pregnancy and breast-feeding:

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.

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 with alcohol

- if you have any further questions, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

- if you get any side effects, tell your doctor or nurse.

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

- other possible side effects:

- the frequency of side effects is either not known or could not be determined from the available data.

- 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.

Children

If your child is going to be given this medicine:

- if it is particularly important to tell your doctor or nurse if your child has cardiovascular disease (heart problems).

- children must be carefully monitored. For infants and babies under 6 months of age this will include monitoring of breathing and oxygen levels.

Warnings and precautions:

Tell to your doctor or nurse before you are given Midazolam Injection.

Adults

Before Midazolam Injection is given, let your doctor or nurse know if:

- you are 60 years of age or over

- you have suffered from a long or breathing disorder

- you have a problem with your kidneys or liver

- you have long-term illness or disability (have a illness that makes you feel very weak, run down and short of energy)

- you have ever been diagnosed as suffering from a personality disorder

- you regularly drink large amounts of alcohol or have had problems with alcohol use in the past

- you regularly take recreational drugs or you have had problems with drug use in the past

- you are pregnant or likely to become pregnant ("Pregnancy and breast-feeding")

- if you have had prolonged treatment during last phase of pregnancy with this medicine, your baby may

- if you have had a stroke or have had problems with blood clotting in the past

- if you have had an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

- 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.

- if you are going to have an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

- if you have had a problem with your kidneys or liver

- if you have had problems with your breathing, you are going to have Midazolam Injection for conscious sedation.

- your baby may be born with problems due to the effect of the medicine on the mother

- there is a risk that your baby may suffer from breathing problems or complications (sometimes causing the breathing to stop)

- if you have a problem with your heart or circulation

- if you have a problem with your breathing

- if you have a problem with your kidneys

- if you have recently used or might use any other medicines.

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

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

- if you suffer from a long or breathing disorder

- if you have a problem with your kidneys or liver

- if you have long-term illness or disability (have a illness that makes you feel very weak, run down and short of energy)

- if you have ever been diagnosed as suffering from a personality disorder

- if you regularly drink large amounts of alcohol or have had problems with alcohol use in the past

- if you regularly take recreational drugs or you have had problems with drug use in the past

- if you are pregnant or likely to become pregnant ("Pregnancy and breast-feeding")

- if you have had prolonged treatment during last phase of pregnancy with this medicine, your baby may

- if you have had a stroke or have had problems with blood clotting in the past

- if you have had an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

- 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.

- if you are going to have an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

- 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.

- if you are going to have an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

- 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.

- if you are going to have an inhaled anaesthetic (one that you breath in) for an operation or for dental treatment, it is

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

Midazolam injection contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

4. POSSIBLE SIDE EFFECTS

Use all medicines, this medicine can cause side effects, although not everyone gets them.

Serious side effects

Stop having midazolam injection and see your doctor straight away if you notice any of the following side effects.

There can be life-threatening and you may need urgent medical treatment:

- you think you are going to vomit or have a sudden rush, 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;
- general allergic reactions (skin reactions, heart and blood system reactions, wheezing);
- breathing problems or complications (sometimes causing the breathing to stop;
- reduced alertness - how long this occurs depends on how much midazolam was used. It may cause you to fall asleep. If treatment is stopped suddenly, it may take some time for your body to adjust and return to normal.

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

Not known (frequency cannot be estimated from the available data):

- confusion
- hallucinations (seeing and possibly hearing things that are not really there)
- reduced alertness
- stiffness or locking
- fits (convulsions) due to withdrawal of drug
- skin rash, redness of face and neck (flushing)
- feeling of sick or being sick
- constipation
- eye pain
- fits (convulsions)
- difficulty in breathing

Other people:

- older patients taking benzodiazepines medicines have a higher risk of falling and breaking bones.
- potential 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. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

How to store MIOZADOL INJECTION

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

Do not use the 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.

Do not store above 25ºC.

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 medicines may help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What midazolam injection contains

The active substance is midazolam.

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

What midazolam injection looks like and contents of pack

Midazolam Injection 5mg in 1ml is a clear, colourless or slightly yellow, sterile solution contained in clear glass ampoules (small bottles). Each 1ml 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., 494C, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

B. Braun Melsungen AG, Melsungen 2, 3827 Berlin, Germany.

This leaflet was last revised in June 2018.

LP-106901-01