

## PATIENT INFORMATION LEAFLET

### MIDORYX® (MIDAZOLAM INJECTION 5mg, 10mg BP)

**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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#### IN THIS LEAFLET:

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#### 1. WHAT MIDORYX IS AND WHAT IT IS USED FOR

Active ingredient present in MIDORYX is Midazolam.

Midazolam belongs to a group of medicines called 'benzodiazepines'. Midazolam works quickly to make you feel sleepy or to put you to sleep. It also makes you calm and relaxes your muscles.

##### **Midazolam is used in adults:**

- as a general anaesthetic to put them to sleep or to keep them asleep.

##### **Midazolam is also used in adults and children:**

- to make them feel calm and sleepy if they are in intensive care. This is called

'sedation'.

- before and during a medical test or procedure where they are going to stay awake. It makes them feel calm and sleepy. This is called 'conscious sedation'.
- to make them feel calm and sleepy before they are given an anaesthetic.

#### 2. BEFORE YOU USE MIDORYX

##### **Do not use MIDORYX**

- if you are allergic (hypersensitive) to midazolam or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other benzodiazepine medicines, such as diazepam or nitrazepam.
- if you have severe breathing problems and you are going to have Midazolam for 'conscious sedation'.

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

##### **Warnings and precautions**

Talk to your doctor or nurse before using Midoryx:

- if you are over 60 years of age.
- if you have a long term illness, such as breathing problems or kidney, liver or heart problems.
- if you have an illness that makes you feel very weak, run down and short of energy.
- if you have something called 'myasthenia gravis' where your muscles are weak.
- if you have ever had alcohol problems.
- if you have ever had drug problems.

If any of the above applies to you (or you

are not sure), talk to your doctor or nurse before you use Midoryx.

### **Children**

- Talk to your doctor or nurse if any of the above applies to your child.
- In particular, tell your doctor or nurse if your child has heart or breathing problems.

### **Other medicines and Midoryx**

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Midoryx can affect the way some other medicines work. Also some other medicines can affect the way Midoryx works.

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

- Medicines for depression
- Hypnotic medicines (to help you sleep)
- Sedatives (to make you feel calm or sleepy)
- Tranquilliser medicines (for anxiety or to help you sleep)
- Carbamazepine or phenytoin (these may be used for fits or seizures)
- Rifampicin (for tuberculosis)
- Medicines for HIV called 'protease inhibitors' (such as saquinavir)
- Antibiotics called 'macrolides' (such as erythromycin or clarithromycin)
- Medicines to treat fungal infections (such as ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole)
- Strong pain killers
- Atorvastatin (for high cholesterol)
- Anti-histamines (for allergic reactions)
- St John's Wort (a herbal medicine for depression)

- Medicines for high blood pressure called 'calcium channel blockers' (such as diltiazem)

If any of the above applies to you (or you are not sure), talk to your doctor or nurse before you are given Midoryx.

### **Midoryx with alcohol**

Do not drink alcohol if you have been given Midoryx. This is because it may make you feel very sleepy and cause problems with your breathing.

### **Pregnancy and breast-feeding**

Talk to your doctor before you are given Midoryx if you are pregnant or think you may be pregnant. Your doctor will decide if this medicine is suitable for you.

After you have been given Midoryx, do not breast-feed for 24 hours. This is because Midoryx may pass into your breast milk.

### **Driving and using machines**

After having Midoryx, do not drive or use tools or machines until your doctor says you can.

This is because Midoryx may make you feel sleepy or forgetful. It may also affect your concentration and co-ordination. This may affect you being able to drive or use tools and machines. After your treatment, you must be taken home by an adult who can look after you.

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 taken 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.

#### **Midoryx contain sodium**

Midoryx contains up to 3.47 milligrams of sodium in each millilitre of solution. This should be taken into consideration for patients on a controlled sodium diet.

### **3. HOW TO USE MIDORYX**

Midoryx will be given to you by a doctor or nurse. It will be given to you in a place that has the equipment needed to monitor you and to treat any side effects. This might be a hospital, clinic or doctor's surgery. In particular, your breathing, heart and circulation will be monitored.

Midoryx is not recommended for use in infants and babies under 6 months of age. However, if the doctor feels that it is necessary, it can be given to an infant or baby under 6 months who is in intensive care.

#### **How Midoryx will be given to you**

You will be given Midoryx in one of the following ways:

- By slow injection into a vein (intravenous injection).

- Through a drip into one of your veins (intravenous infusion).
- By injection into a muscle (intramuscular injection).
- Into your back passage (rectum).

#### **How much Midoryx will be given to you**

The dose of Midoryx varies from one patient to another. The doctor will work out how much to give you. It depends on your age, weight and general health. It also depends on what you need the medicine for, how you respond to treatment, and whether you are going to be given other medicines at the same time.

#### **After being given Midoryx**

After your treatment, you must be taken home by an adult who is able to look after you. This is because Midoryx may make you sleepy or forgetful. It may also affect your concentration and co-ordination.

If you are given Midoryx for a long time, such as in intensive care, your body may start to get used to the medicine. This means it may not work as well.

#### **If you use more Midoryx than you should**

Your medicine will be given to you by a doctor or nurse. This means it is unlikely that you will be given too much. However, if you are given too much by mistake, you may notice the following:

- Feeling sleepy and losing your co-ordination and reflexes.
- Problems with speaking and unusual eye movements.
  - Low blood pressure. This may make you feel dizzy or light-headed.
- Slowing or stopping of your breathing or heart beat and being unconscious (coma).

### **If you stop using Midoryx**

If you are given Midoryx for a long time, such as in intensive care, you may get withdrawal symptoms when you stop being given the medicine. These include:

- Mood changes
- Fits (convulsions)
- Headache
- Muscle pain
- Problems with sleeping (insomnia)
- Feeling very worried (anxious), tense, restless, confused or bad tempered (irritable).
- Seeing and possibly hearing things that are not really there (hallucinations).

Your doctor will lower your dose gradually. This will help to stop withdrawal symptoms from happening to you.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported but their frequency is not known and cannot be estimated from the available data.

**Stop having Midoryx and see a doctor straight away if you notice any of the following side effects. They can be life-threatening and you may need urgent medical treatment:**

- A severe allergic reaction (anaphylactic shock). The 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 also have shortness of breath, wheezing or trouble breathing.
- Heart attack (cardiac arrest). The signs may include chest pain.

- Breathing problems, sometimes causing the breathing to stop.

- Muscle spasm around the voice box, causing choking.

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- Heart attack (cardiac arrest). The signs may include chest pain.

- Breathing problems, sometimes causing the breathing to stop.

- Muscle spasm around the voice box, causing choking.

Life-threatening side effects are more likely in adults over 60 years, and in people who already have breathing or heart problems. These side effects are also more likely if the injection is given too fast or at a high dose.

### **Other possible side effects**

#### **Nervous system and mental problems**

- Being less alert
- Feeling confused
- Feeling very happy or excited (euphoria).
- Feeling tired or sleepy or being sedated for a long time.
- Seeing or possibly hearing things that are not really there (hallucinations).
- disturbance of consciousness (delirium)
- Headache
- Feeling dizzy
- Difficulty co-ordinating muscles
- Fits (convulsions) in premature and new-born babies.
- Temporary memory loss. How long this lasts depends on how much Midazolam

you were given. Occasionally this has lasted for a long time.

- Feeling agitated, restless, angry or aggressive. You may also have muscle spasms or shaking of your muscles that you cannot control (tremors). These effects are more likely if you have been given a high dose of Midoryx or if it has been given too quickly. It is also more likely in children and elderly people.

#### **Heart and circulation**

- Fainting
- Slow heart rate
- Redness of the face and neck (flushing)
- Low blood pressure. This may make you feel dizzy or light-headed.

#### **Breathing**

- Hiccups
- Being short of breath

#### **Mouth, stomach and gut**

- Dry mouth
- Constipation
- Feeling sick (nausea) or being sick (vomiting)

#### **Skin**

- Feeling itchy
- Rash, including a lumpy rash (hives)
- Redness, pain, blood clots or swelling of the skin where the injection was given.

#### **General**

- Allergic reactions including skin rash and wheezing.
  - Withdrawal symptoms)

#### **Elderly people**

- Older people taking benzodiazepine medicines, like Midoryx, have a higher risk of falling and breaking bones.
- Life-threatening side effects are also more likely to happen in adults over 60 years.

#### **5. HOW TO STORE MIDORYX**

- Your doctor or pharmacist is responsible for storing Midoryx. They are also responsible for disposing of any unused Midoryx correctly.
- 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 label/carton after "EXP:". The expiry date refers to the last day of that month.
- Do not use this medicine if the small glass bottle (ampoule/vial) or packaging is damaged.
- Keep the ampoules/vials in the outer carton in order to protect from light.
- Do not store above 25°C. Do not freeze.

#### **6. FURTHER INFORMATION**

##### **What MIDORYX contains**

- The active substance is midazolam (as midazolam hydrochloride).

In Midoryx 5 mg/ml, 10mg/ml each 1 ml of liquid contains 5 mg, 10mg of midazolam (as midazolam hydrochloride) respectively.

Also available in 1mg/ml, 2mg/ml strengths

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

##### **What Midoryx looks like and contents of the pack**

Midazolam comes in a colourless glass ampoule/vial (small bottle). It is a clear, colourless, liquid (solution for injection/infusion or rectal solution).

The following pack sizes are available for Midazolam 5 mg/ml, 10mg/ml solution for injection:

- 1 ml glass ampoules: packs of 5, 10, 25, 50 or 100
- 2 ml glass ampoules: packs of 5, 10, 25, 50 or 100•
- 3 ml glass ampoules: packs of 5, 10, 25, 50 or 100•
- 5 ml glass ampoules: packs of 5, 10, 25, 50 or 100
- 10 ml glass ampoules: packs of 5, 10, 25, 50 or 100
- 18 ml glass ampoules: packs of 5, 10, 25, 50 or 100

Not all pack sizes may be marketed

**Manufactured By:**

TAJ PHARMACEUTICALS Ltd.  
Mumbai, INDIA

**Marketed By:**

TAJ PHARMA INDIA LTD.  
CRESCENT, SAHAR AIRPORT ROAD,  
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**This leaflet was last revised in AUGUST 2015.**