

## PATIENT INFORMATION LEAFLET

### SEDOZOLAM 15 mg/3 ml Solution for Injection or Infusion

Sterile, apyrogen

**It is administered intravenous and intramuscular or rectal.**

- **Active substance:** Each ampoule contains 15.0 mg midazolam in 3 ml solution. Each milliliter contains 5 mg midazolam.
- **Excipients:** disodium EDTA, sodium chloride, hydrochloric acid, water for injection.

**Before using this medicine, please read this Patient Information Leaflet carefully, because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, consult your doctor or your pharmacist.
- This medicine has been prescribed for you personally; you should not pass it on to others.
- During use of this medicine please tell to your doctor that you use this medicine when you go to the doctor or hospital.
- Follow the information in the leaflet exactly. Do not use **lower** or **higher** dosages rather than recommended dosages regarding the medicine.

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#### **1. What is SEDOZOLAM and what it is used for?**

• SEDOZOLAM ampoule is a benzodiazepine from imidazobenzodiazepine group. It is a fast acting medicine used to start sleeping (calm, numbness or drowsiness) and to reduce excitement, muscle contractions and spasms. The drug is administered by intravenous injection, injection with drops (infusion), intramuscular or rectal administration.

• SEDOZOLAM is a clear and colorless sterile ampoule solution with midazolam as the active ingredient. 1 ml of solution contains 5 mg of midazolam. Each ampoule contains 15 mg of midazolam in 3 mL of solution. Each box has 3 or 5 glass ampoule of 15 mg / 3 ml.

This medicine is used for examinations and to put to sleep or to keep sleep in adults and children during treatment. It is used as medication before the intervention, to sedate the patients before the treatment and to put the patients in the intensive care unit to sleep. Midazolam can be used alone or in combination with other medicines used in anesthesia.

## 2. What you need to know before you use SEDOZOLAM?

### Do not use SEDOZOLAM:

- If you are allergic (hypersensitive) to any group of drugs known as benzodiazepines or any of the adjuvants contained in the drug.
- If you have severe respiratory distress or respiratory failure and are in a state of conscious sleep (sleepiness and calmness).

### Take special care with SEDOZOLAM

#### If;

- You are over 60 years of age,
- You have a constant respiratory distress problem,
- You are Myasthenia gravis patient (a disease caused by muscle weakness)
- Your liver, kidney or heart function is impaired
- You have alcohol or drug addiction
- Your doctor has prescribed a medication to you other than prescribed (*see combination with other medications*)
- You are pregnant or you are likely to be pregnant.

In all cases, inform your doctor.

The use of SEDOZOLAM in children and infants requires special attention. If your child has a heart problem, inform your doctor. Thus your doctor will know that he/she should watch you or your child carefully and will adjust the dose specially.

SEDOZOLAM can reduce your breathing and heart rate when administered intravenously. In rare cases, it may cause your breathing or your heart to stop. To avoid this, the doses are given slowly and as low as possible.

When SEDOZOLAM given before intervention, patients' responses to midazolam are highly variable. For this reason, you will be very strictly checked to make sure that you are getting the correct dose.

Please consult your doctor if these warnings apply to you at any time in the past.

### Usage of SEDOZOLAM with food and drinks

Alcohol may increase the sleep-inducing effects of SEDAZOLAM and therefore should be avoided. You do not drink alcohol until your doctor allows it.

### Pregnancy

*Before usage of this medicine, please consult to your doctor or pharmacist.*

- If you are pregnant and think you might be pregnant, or plan to become pregnant, please consult your doctor. Your doctor will decide whether or not to take medicine.
- If your doctor decides to give you the medicine, your baby may have irregular heartbeats, low body temperature, breathing, nourishment and sucking difficulties during the last months of pregnancy, during the birth or during the cesarean section. You may be under the risk of sucking vomit into your lungs.
- SEDOZOLAM has not enough information on the safety during pregnancy. Benzodiazepines should not be used during pregnancy unless there is a safer alternative.

*If you have been noticed that you are pregnant during treatment, immediately consult to your doctor or pharmacist.*

### **Lactation**

*Before usage of this medicine, consult to your doctor or pharmacist.*

SEDOZALAM can get into breast milk, so you should not breastfeed for 24 hours after using the medicine.

### **Driving and using machines**

The medication can make you sleepy, forgetful or may affect your concentration and coordination. This can affect your performance (eg. driving) at your job skill level. Your doctor will decide when you will be able to resume such work. You must be accompanied by a responsible adult until you go home following the application (always).

### **Important information about excipients in contents SEDOZOLAM:**

SEDOZOLAM contains less than 23 mg of sodium in a 15mg/3mL dose. Namely, it does not contain sodium actually.

### **Other medicines and SEDOZOLAM**

At the same time, using more than one medicine may increase or decrease the effectiveness of the medication. For example; sedatives, antidepressants, narcotic analgesics (very powerful painkillers), antiepileptics (for the treatment of epilepsy), anesthetics and some antihistamines (for allergy treatment) may increase the effects of SEDOZOLAM.

In addition, antifungals, antibiotics, blood pressure and drugs used in the treatment of digestive problems and some of drugs used in the treatment of AIDS and HIV may increase the effects of midazolam.

*If you have been taking prescribed or non-prescribed medicines now or in the past, please inform your doctor or pharmacist.*

## **3. How to use SEDOZOLAM?**

### **Instructions for use and for frequency of dosage/administration**

Your doctor will decide the proper dosage for you. The doses may be adjusted for planned treatment and the required sedation. Your age, your weight, your general health condition, your response to the medication and other medications used at the same time will affect your intake dose.

If you are using strong painkillers, you should use them first, then you should take the SEDOZOLAM dose that customized for you.

### **Administration route and method**

Midazolam is administered slowly by intravenous, drop (infusion), into the muscle (intramuscular) or rectal application.

### **Different age groups**

#### **Use in children and elderly**

Your doctor will decide the proper dose for you and your child.

### **Special conditions**

### **Renal impairment**

There is no need for dose adjustment.

### **Liver impairment**

In the case of liver failure your doctor may need to reduce the dose.

*If you think that the effect of SEDOZOLAM is too high or too low, please consult your doctor or your pharmacist.*

### **If you forget to use SEDOZOLAM**

Sedozolam is administered under doctor control.

*Do not take a double dose to make up for a missed dose.*

### **If you receive more SEDOZOLAM than you should**

Sedozolam is administered by health professional in hospital. If you think you have been given too much medicine, you should tell your doctor.

*If you have used SEDOZOLAM more than you need, you should talk to a doctor or pharmacist.*

### **Effects may be seen when treatment with SEDOZOLAM is stopped**

#### **Long-Term Therapy**

In patients treated with long periods with SEDOZOLAM, tolerance may develop (medicines may be less effective) or may vary by medicine.

After prolonged treatment (as in intensive care unit), the following deprivation symptoms may appear: Headache, muscle aches, restlessness, tension, discomfort, mood swings, irritability, drowsiness, mood changes, hallucinations and contractions, mental blur, irritability, insomnia. If these effects happen to you, your doctor will gradually decrease your dose.

If you have any further questions about the use of this medicine, please consult your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, there may be side effects in people sensitive to substances in the SEDOZOLAM content.

**If any of the followings occur, stop using SEDOZOLAM and IMMEDIATELY inform your doctor or go to the emergency service of the nearest hospital:**

- Temporary memory loss. How long it takes depends on the dose of SEDOZOLAM and you can experience it after the treatment. It has been reported at some special occasions.
- Respiratory complications (sometimes causing heart or respiratory arrest)
- Blood and circulatory system disorders
- Low blood pressure
- Changes in heart rate and pressure state
- Fainting
- Difficulty in breathing
- Blockage of the breathing tube
- Anaphylactic shock (life-threatening allergic reaction)

Life-threatening events are more common in elderly people with previous respiratory failure or

heart problems, especially when the injection is performed too quickly or when administered at high doses.

Breathing problems are likely to develop in 6-month-old patients, so they will be given little doses, breathing and oxygen levels should be observed.

**If you notice any of the following, report it to your doctor immediately or contact the emergency department of your nearest hospital:**

- Rash
- Allergic reaction
- Difficulty managing muscles
- Agitation
- Muscle spasms and muscle tremors
- Sick feeling
- Vomiting
- Constipation

These are serious side effects and medical treatment may be required.

**If you notice one of below side effects, tell your doctor.**

- Itching
- Long-lasting calm
- Drowsiness
- Reduced attention
- Mental blur
- Intensive happiness
- Hallucinations
- Fatigue
- Headache
- Dizziness
- Restlessness, excitement
- Grudge, violence, feeling of attack
- Hiccups
- Dry mouth
- Wheezing
- Redness, pain in the injection site
- Swelling and redness in veins
- Blood coagulation

These are the minor side effects of SEDOZOLAM.

These were observed when a higher dose was given or when the drug was administered very quickly.

Children and the elderly are more sensitive to these reactions. Contractions in early-born and newborn babies have been reported more frequently.

After prolonged intravenous use, may become addicted to midazolam. It is important to slow down the dosage of the drug to prevent deprivation symptoms, including medication withdrawal contractions.

*If you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.*

#### Reporting of side effects

If you feel any side effects not listed in this leaflet talk to a doctor, pharmacist or nurse. Furthermore report the side effects you feel by clicking “Reporting Medicine Side Effect” in [www.titck.gov.tr](http://www.titck.gov.tr) or by calling 0 800 314 00 08 side effect report line Turkey Pharmacovigilance Center. By reporting side effects, you can help provide more information on the safety of this medicine

### **5. Storage of SEDOZOLAM**

*Keep out of the sight and reach of children and store in the original pack.*

- Store at room temperature, below 25°C.
- Protect from light.
- SEDOZOLAM ampoules should not be frozen due to explosion possibility. At room temperature a soluble precipitate can be seen by shaking.
- SEDOZOLAM ampoules are for single use.
- The solution should be visually inspected before use. Only particle-free and clear solutions should be used.
- After diluting the preparation with the following solvents, it is stable 3 days at 2-8°C storage condition and for 24 hours at 25°C storage condition.

- Ringer solution
- Hartman solution
- 5% dextrose solution
- 10% dextrose solution
- 0.9% sodium chloride solution

Microbiologically, it should be used immediately after dilution. Dilution is stable for 24 hours at 2-8°C unless dilution is prepared under controlled and validated aseptic conditions.

**Please use SEDOZOLAM in accordance with expiry date.**

*Do not use SEDOZOLAM after expiry date written on the box.*

#### ***Registration holder:***

Monemfarma İlaç San. ve Tic. A.Ş.  
Anıttepe Mah. Turgut Reis Cad. No: 21, Tandoğan – Ankara  
Tel: 0312 230 29 29  
Faks: 0312 230 68 00

#### ***Manufacturing site:***

İDOL İLAÇ DOLUM SAN. ve TİC. A.Ş.  
Davutpaşa Cad. CebeAli Bey Sok.No:20  
Topkapı / İSTANBUL

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