

PATIENT INFORMATION LEAFLET

SEDEVER 15 mg/3 mL I.V./I.M./Rectal ampoule solution for injection and infusion

Sterile

For intramuscular, intravenous or rectal administration.

- **Active Ingredient:** Each 3 mL ampoule contains 15 mg midazolam.
- **Excipients:** Sodium chloride, hydrochloric acid, sodium hydroxide, water for 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 pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low doses** other than the recommended dosage.*

What is in this leaflet:

1. *SEDEVER is and what it is used for?*
2. *What you need to know before you use SEDEVER*
3. *How to use SEDEVER?*
4. *Possible side effects*
5. *How to store SEDEVER*

1. What SEDEVER is and what it is used for?

- SEDEVER is a benzodiazepine of the imidazobenzodiazepine group. It is a fast-acting drug used to induce sleep (calming down, lethargy or sleepy state) and to reduce excitement, muscle contractions and spasms. The drug is administered by intravenous injection (intravenous), drip injection (infusion), intramuscular injection or rectal administration.
- SEDEVER is a clear, colorless, particle-free sterile solution whose active ingredient is midazolam. Each ampoule contains 15 mg of midazolam in 3 mL of solution (5 g/mL). Each box contains 5 glass ampoules of 3 mL.
- This drug is used for drowsiness and numbness in adults and children during

examinations and treatment. It is used as a drug given before the intervention, to soothe patients before treatment and to put patients in the intensive care unit to sleep. Midazolam can be used alone or in combination with other drugs used in anesthesia.

2.What you need to know before you use SEDEVER

DO NOT USE SEDEVER;

If;

- You are allergic (hypersensitive) to the group of drugs known as benzodiazepines or to any of the excipients contained in the drug.
- You have severe breathing difficulties or respiratory failure and are consciously drowsy (drowsiness and calmness).

USE SEDEVER CAREFULLY if you;

If;

- You are over 60 years old,
- You have persistent breathing problems,
- You have myasthenia gravis (a disease caused by muscle weakness),
- You have liver, kidney or heart functions,
- You are addicted to alcohol or drugs,
- You are using any medication other than those prescribed by your doctor (See Section Using with other medicines),
- You are pregnant or possibly pregnant,

Inform your doctor in all these cases.

The use of SEDEVER in children and infants requires special attention. If your child has a heart problem, inform your doctor. Thus, your doctor will know that you or your child need careful observation and will adjust the dose specifically.

When SEDEVER is administered intravenously, it can reduce your breathing and heart rate. In rare cases, it may cause your breathing or heart to stop. To prevent this from happening, doses are given slowly and in as low amounts as possible.

Patients' response to midazolam is highly variable when SEDEVER is given prior to intervention. Therefore, you will be very tightly controlled to make sure you get the correct dose.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Use of SEDEVER with food and drink

- Alcohol can increase the sleep-inducing effects of SEDEVER and therefore its use should

be avoided. Do not drink alcohol until your doctor gives permission.

Pregnancy

Consult your doctor or pharmacist before using this medication.

- If you are pregnant, think you may be pregnant, or are planning to become pregnant, please consult your doctor. Your doctor will decide whether to take the medicine or not.
- If your doctor decides to prescribe the drug, your baby may have irregular heartbeats, low body temperature, breathing, feeding, and sucking difficulties in late pregnancy, delivery or cesarean section. You may be at risk of pulling vomit into your lungs.
- There is not enough information about the safety of SEDEVER during pregnancy. Benzodiazepines should not be used during pregnancy unless there is a safer alternative.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

- SEDEVER can pass into breast milk, so you should not breast-feed for 24 hours after taking the medicine.

Driving and using machines

The medication may make you drowsy, forgetful, or affect your concentration and coordination.

This can affect your performance in skilled jobs (eg using or driving).

Your doctor will decide when to start this type of work again. After the administration (always) you must be accompanied by a responsible adult until you get home.

Important information about some of the excipients in SEDEVER

SEDEVER contains less than 23 mg of sodium, but due to the dose it contains, no adverse effects related to sodium are expected at this dose.

Using other medicines

More than one drug used at the same time can increase or decrease the effect of drugs taken.

For example; sedatives, hypnotics (sleeping pills), sedatives, antidepressants, narcotic analgesics (very strong painkillers), antiepileptics (for epilepsy treatment), anesthetics and some antihistamines (for allergy treatment) can aggravate the effects of SEDEVER.

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

If you are currently using any prescription or non-prescription medicine or have used it recently, please inform your doctor or pharmacist about them.

3.How to use SEDEVER

Instructions for use and dose/administration frequency:

Your doctor will decide the appropriate dose for you. Doses may differ depending on the planned treatment and sedation required. Your age, weight, general health condition, response to medication and other medicines used at the same time will affect the dose taken.

If you are using strong pain relievers, you should use them first and then take the SEDEVER dose specifically adjusted for you.

Method of administration

SEDEVER is administered slowly by intravenous injection (intravenous), drip injection (infusion), intramuscular injection or rectal administration.

Various age groups

Use in children and elderly:

Your doctor will decide the appropriate dosage for you and your child.

Special cases of use:

Renal failure:

No dose adjustment is required.

Hepatic failure:

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

If you have an impression that the effect of SEDEVER is too strong or too weak, talk to your doctor or pharmacist.

If you use more SEDEVER than you should

Your medicine will be administered by a doctor. If you think you have been given too much medication, you should tell your doctor.

Talk to a physician or pharmacist if you have used more SEDEVER than you should use.

If you forget to use SEDEVER

It is not valid as it will be administered by your doctor.

Do not take double doses to make up for forgotten doses.

Effects that may occur when treatment with SEDEVER is terminated

Long Term Treatment

Patients on long-term treatment with SEDEVER may develop intolerance (drugs may be less effective) or vary by medication.

The following withdrawal symptoms may occur after prolonged treatment (such as in the intensive care unit): Headache, muscle aches, restlessness, tension, discomfort, confusion, irritability, inability to sleep, mood changes, hallucinations and convulsions. If you have these

effects, your doctor will gradually reduce the dose.

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

4. Possible side effects

As with all medicines, there may be side effects in people who are sensitive to the ingredients of SEDEVER.

If you notice any of the following, stop using SEDEVER and inform your doctor IMMEDIATELY, or apply to the emergency service of the nearest hospital:

- Temporary memory loss. How long this will take depends on the SEDEVER dose you take, and you may experience this after treatment. It has been reported in some specific cases.
- Respiratory complications (sometimes causing heart or respiratory arrest)
- Blood and circulatory system disorders
- Low blood pressure
- Changes in heart rate and pressure
- Fainting
- Shortness of breath
- Obstruction of the windpipe
- Anaphylactic shock (life-threatening allergic reaction)

Life-threatening events are more common in the elderly with pre-existing respiratory failure or heart problems, especially when the injection is given too quickly or in high doses.

Respiratory problems are likely to develop in patients younger than 6 months, so they will be given a dose-by-little dose to monitor their breathing and oxygen levels.

If you notice any of the following, inform your doctor immediately or contact the emergency department of your nearest hospital:

- Rash
- Allergic reaction
- Difficulty managing muscles
- Agitation
- Muscle spasms and muscle tremors
- Feeling sick
- Vomiting
- Constipation

These are all serious side effects. Emergency medical attention may be required.

If you notice any of the following, tell your doctor:

- Itching
- Prolonged calming
- Drowsiness
- Reduced attention
- Mind blur
- Intense happiness
- Hallucinations
- Fatigue
- Headache
- Dizziness
- Unrest, excitement
- Feeling of grudge, violence, fighting, aggression
- Hiccups
- Dry mouth
- Wheezing
- Redness and pain at the injection site
- Swelling and redness in the veins
- Blood clotting

These are mild side effects of SEDEVER.

These have mostly been observed when high doses were given or when the drug was administered too quickly. Children and elderly people are more susceptible to these reactions. Contractions have been reported more frequently in preterm and newborn babies.

After long-term intravenous use, it may become dependent on midazolam. To avoid withdrawal symptoms, including withdrawal spasms, it is important that you taper off the medication dose gradually.

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store SEDEVER

Keep SEDEVER out of the reach and sight of children and within its packaging.

- Store at room temperature below 25 ° C.

- After dilution, it should be stored within 24 hours at room temperatures and 3 days if stored between 2-8°C.
- Protect from light.
- SEDEVER ampoules should not be frozen due to the possibility of explosion. At room temperature, a precipitation may be seen which dissolves with agitation.
- SEDEVER ampoules are for single use only.
- Before use, the solution should be inspected visually. Only clear solutions without particles should be used.

Use in compliance with the expiry date.

Do not use SEDEVER after the expiry date which is stated on the packaging.

Marketing Authorization Holder

HAYER FARMA İlaç A.Ş.

Akbaba Mah. Maraş Cad. No: 52/2/1

Beykoz / İstanbul

Manufacturer:

Osel İlaç Sanayi ve Ticaret A.Ş.

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This patient information leaflet approved in 31/08/2015.