

## PATIENT INFORMATION LEAFLET

### ANESED-R 0.5 mg/5 mL Solution For I.V. Injection

Administered intravenously

Sterile

- **Active Substance:** Each 5 mL ampoule contains 0.5 mg (0.1 mg/ml) flumazenil.
- **Excipients:** EDTA, glacial acetic acid, sodium chloride, sodium hydroxide, injectable water.

**Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully.**

**Because, this leaflet includes important information for you.**

- *Keep this PATIENT INFORMATION 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

#### **What is in this leaflet**

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

#### ***1. What ANESED-R is and what it is used for?***

ANESED-R is a injection or infusion solution including flumazenil as active ingredient, 1 mL of solution include 0.1 mg flumazenil. Each ampoule involve 0.5 mg flumazenil in 5 mL solution. Each package have 0.5 mg/5 mL 5 ampoule.

ANESED-R reverse the effect of benzodiazepines which is used as strong sleep initiator. It is given into the vein slowly or at one time by continuous injection. Although its effect disappears within a few hours and the state of sleep reappears, it acts quickly.

ANESED-R is used to completely or partially reverse the sedative effects of benzodiazepines. Therefore, it is used in anesthesia and intensive care for the following indications:

- *In anesthesia:* Termination of general anesthesia using benzodiazepines for initial (induction) and maintenance. Reversing the calming effects of benzodiazepines used in short diagnostic and therapeutic procedures in both inpatients and outpatients.

- In intensive care unit and approach to loss of consciousness of unknown cause: ANESED-R is used to diagnose or determine whether benzodiazepine intoxication is present.

In cases of overdose with benzodiazepines, it can also be used to specifically restore the central effects of benzodiazepines.

## **2. What you need to know before use ANESED-R?**

### **DO NOT use ANESED-R in the following situations:**

- If you are allergic to flumazenil benzodiazepines (e.g., diazepam, midazolam, temazepam) or any of the other ingredients
- If you have epilepsy or you are receiving benzodiazepine treatment for a long time
- If you are taking benzodiazepine and some antidepressants (eg amitriptyline, imipramine, dothipine hydrochloride)
- If you are taking benzodiazepine for the control of potentially life-threatening situations

### **USE ANESED-R CAREFULLY in the following cases**

- If you have head trauma
- If you have a history of anxiety, anxiety, or concern about the operation
- If you have a history of anxiety or concern about the operation
- If you suffer from coronary heart disease, epilepsy, or severe liver disease
- If you are taking any medication other than prescribed by your doctor. This is very important because using more than one drug at the same time can increase or decrease the effects of drugs. You should tell your doctor, especially if you are taking zopiclone or some antidepressant drugs.

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

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

If you are pregnant, think you may be pregnant or plan to become pregnant, please consult your doctor. Your doctor will decide whether to take the medicine.

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

### **Lactation**

*Consult your doctor or pharmacist before using this medication.*

ANESED-R can pass into breast milk. If you are breastfeeding, you should avoid using this medicine unless there is an emergency.

### **Ability to drive and use machines**

Do not drive or use the machine within 24 hours of taking this medicine; Do not engage in any activity that requires physical or mental alertness, as ANESED-R may prevent you from driving safely.

### **Important information about some of the excipients contained in ANESED-R**

This medicinal product contains less than 1 mmol (23 mg) of sodium per ampoule; that is, it does not contain sodium.

### **Use in combination with other drugs**

The effects of zopiclone, triazolopyridazines and non-benzodiazepine agonists on benzodiazepine receptors are also blocked by ANESED-R. The pharmacokinetics of benzodiazepine agonists remain unchanged, but vice versa.

*If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.*

### **3. How to use ANESED-R?**

#### **• Instructions regarding correct use and dosage/administration frequency:**

This medication should only be administered by an experienced physician.

Your doctor will determine the dose of your medicine and apply it to you depending on your illness. The doses will vary depending on the method you are taking and the degree of sedation.

Your body weight, age, general health, and response to the drug will also affect the dose.

- The initial dose was 0.2 mg administered by slow injection into the vein in 15 seconds. If the desired consciousness is not reached within 60 seconds, a second dose of 0.1 mg may be injected. If necessary, this dose may be repeated every 60 seconds, provided that if and only if the total dose does not exceed 1 mg (2 mg under intensive care) until the consciousness is reached. Usually the dose administered is 0.3-0.6 mg.
- If drowsiness reappears, intravenous medication may be administered at a rate of 0.1-0.4 mg per hour by slow continuous injection until the desired consciousness is reached. If there is no significant improvement in consciousness and independent breathing after repeated doses, your doctor will stop using ANESED-R and try another method to regain consciousness.
- If you are treated with benzodiazepines, ANESED-R can cause syndromes such as anxiety, anxiety, dizziness and sweating. Deprivation syndromes may occur even if you

have stopped benzodiazepine therapy in the weeks before you started using ANESED-R. To reduce this, your doctor may administer a slow injection of diazepam or midazolam (benzodiazepines) into the vein.

**Method of administration:**

ANESED-R should only be administered intravenously by an anesthesiologist or an experienced physician.

**Different age groups:**

**Usage in children:**

ANESED-R should only be given to children if the doctor considers it appropriate.

**Usage in elderly**

If you are older, your ANESED-R dose should be adjusted specifically.

**Conditions of special use:**

**Renal failure**

No special use.

**Liver failure**

If you have a liver problem, your ANESED-R dose should be adjusted specifically.

*Talk to your doctor or pharmacist if you have the impression that the effect of ANESED-R is too strong or too weak.*

**If you use more ANESED-R than you should:**

If you feel that you have been given more than necessary ANESED-R, contact your doctor, pharmacist or hospital as soon as possible, even if you do not feel any illness.

*If you use more ANESED-R than you should, talk to a doctor or pharmacist.*

**If you forget to use ANESED-R:**

Do not take a double dose to compensate forgotten dose.

**If ANESED-R treatment stopped, effects may occur:**

The ANESED-R treatment is terminated when your consciousness is fully opened. However, since the effects of ANESED-R can disappear immediately and you may need repeated doses, you should stay under close medical supervision until the drowsiness completely disappears.

**4. Possible side effects**

Like all other medicines, ANESED-R may cause side effects in patients with hypersensitivity to any component of the drug.

ANESED-R is well tolerated in children and adults. ANESED-R was well tolerated, even in amounts exceeding the recommended dose.

**If one of following occurs, stop using ANESED-R and tell your doctor immediately or consult nearest emergency room:**

- Spasm (convulsions) may occur in patients with known epilepsy or severe liver (hepatic) impairment.
- Sudden and severe allergic reactions may occur with the use of ANESED-R. Urticaria (slowly itchy, red skin spots than normal skin), sudden swelling of hands, feet and ankles, or swelling on the face, lips, mouth or throat making it difficult to swallow and breathe.
- Slow heart rate (bradycardia), chest pain, confusion, hypertension, severe increase in heart rate (tachycardia)

These are all very serious side effects. If you have one of these, you have a serious allergy to ANESED-R. You may need urgent medical attention or hospitalization. All of these very serious side effects are very rare.

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

- Nausea, vomiting, flushing, severe inflammation
- If you wake up too quickly, the ANESED-R can cause a feeling of agitation or fear.
- May cause increases in blood pressure and heart rate in intensive care unit patients.
- Difficulty in breathing (dyspnea), excessive deep and prolonged breathing (hyperventilation). All these are serious side effects. Emergency medical attention may be required. Serious side effects are very rare.
- Seizures (convulsions) may occur after long-term benzodiazepine treatment, or if you have taken a large dose of several drugs and have epilepsy or severe hepatic impairment.

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

- If you discontinued benzodiazepine therapy in the weeks before you started using ANESED-R, withdrawal syndromes such as anxiety attacks, dizziness, excessive sweating (diaphoresis) may develop. These symptoms can be treated with a slow diazepam or midazolam injection made to the vessel by your doctor.
- Dry mouth, headache, irritability, insomnia, unusual crying, being overly happy, depression, emotional variability, voluntary movements disorder (ataxia), loss of self, tear increase, dissatisfaction (dysphoria), paranoia, fatigue, dizziness, injection pain, chills, tremor, weakness, abnormal perception (paresthesia)

- Visual disturbances (normal and blurred vision)
- Insomnia, fatigue
- Abnormal hearing, transient hearing impairment, tinnitus
- Anesthetized injection of ANESED-R can rarely cause symptoms such as anxiety, palpitation and fear. These undesirable effects usually do not require special treatment.
- In patients who have been on benzodiazepine for a long time, rapid ANESED-R injection may cause withdrawal symptoms, even if treatment has been discontinued a few weeks before the administration of ANESED-R.
- In patients with a history of panic disorder, ANESED-R may exacerbate panic attacks.

*Inform your doctor or pharmacist if you encounter any side effects not mentioned in these instructions for use.*

### **5. How to store ANESED-R?**

*Store ANESED-R in its original packaging and keep out of the reach and sight of children.*

Store at room temperature below 25°C.

The ANESED-R should be used within 24 hours after withdrawal to the injector or after mixing with normal saline or 5% dextrose, provided that it is stored at room temperature below 25 ° C.

For optimum sterility; The ANESED-R should remain in the ampoule just before use.

### **Use in accordance with expiration dates.**

*Do not use ANESED-R after the expiry date on the packaging.*

Do not use ANESED-R if you notice defects in the product and / or packaging.

### ***Marketing Authorization Holder:***

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