

PATIENT INFORMATION LEAFLET

ADRENALINE Osel 1 mg/mL IM/IV/SC solution for injection

Sterile

Administered in muscle, vein, heart, trachea or subcutaneously.

- **Active Ingredient:** Each 1 mL ampoule contains 1 mg adrenaline.
- **Excipients:** Sodium chloride, sodium metabisulfite and water for injection.

Read all of this PATIENT INFORMATION 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. **ADRENALINE OSEL is and what it is used for?**
2. **What you need to know before you use ADRENALINE OSEL**
3. **How to use ADRENALINE OSEL?**
4. **Possible side effects**
5. **How to store ADRENALINE OSEL**

1. What ADRENALINE OSEL is and what it is used for?

ADRENALINE OSEL is presented in boxes of 10 and 100 ampoules containing 1 mg of adrenaline in one ampoule. Ampoules contain colorless-light yellow clear solution. Adrenaline is used in the following situations:

- Cardiac arrest and cardiopulmonary reanimation:

If artificial respiration and open or closed heart compression do not work, ADRENALINE OSEL can be administered intravenously, into the heart or trachea after intravenous sodium bicarbonate is given.

- Anaphylactic shock (hypersensitivity reaction with low blood pressure) and acute (sudden onset) allergic reactions

It is used as a physiological antagonist of histamine against angioedema (non-itchy swelling and reddening of the skin as a result of allergies), drug and serum reactions, insect bites and other allergens. If there is shock, it is not administered subcutaneously. In addition, the patient in shock should be given an intravenous H₁ receptor antagonist (chlorpheniramine).

- It is administered under the skin in acute (sudden) asthma attacks and bronchospasm (contraction of the bronchi and bronchioles).
- Stopping capillary (superficial) bleeding in the skin and mucous membranes. It is given locally as a solution.
- Extend the duration of action of local anesthetics (drugs providing regional anesthesia).

It is added as a vasoconstrictor by dentists.

2.What you need to know before you use ADRENALINE OSEL

DO NOT USE ADRENALINE OSEL;

If;

- you have hypertension (high blood pressure),
- your thyroid gland is overactive,
- you have coronary insufficiency (the condition that the blood vessels feeding the heart cannot carry enough blood to the heart),
- you have diabetes,
- you have pheochromocytoma (a tumor that develops in the adrenal gland),
- Subaortic stenosis (narrowing of the right ventricular outflow tract of the heart),
- Hypovolemic shock (inability of the heart to pump enough blood to the body due to the decrease in blood volume) (except anaphylactic shock),
- you have organic heart disease (diseases caused by the heart's own structure),
- you have arrhythmia (if you have a rhythm disorder),
- In heart dilatation (heart enlargement),
- Organic brain damage (diseases caused by the structure of the brain),
- you have cerebrovascular disease (diseases related to brain vessels),
- you have narrow-angle glaucoma (an eye disease that causes sudden blurred vision, pain and redness),
- you took cyclopropane or halogenated hydrocarbon derivative anesthetic for general anesthesia,

- you have hypersensitivity to adrenaline,

In addition, when mixed with local anesthetics, it should not be used on the fingers, ear, nose and genital (reproductive organs) areas.

USE ADRENALINE OSEL CAREFULLY if you;

Use the medicine carefully in the following situations;

- Acidosis (increased acidity in the blood),
- Hypoxia (decreased amount of oxygen to tissues),
- Chronic (long-term) asthma and emphysema (the disease caused by the stretching and widening of the air sacs in the lungs and showing the symptom of shortness of breath).
- Cardiovascular diseases,
- You will be operated under general anesthesia.

It should be used with caution in elderly and psychoneurotic patients as well as in cerebral arteriosclerosis (arteriosclerosis seen in brain vessels).

It may cause sulfite allergy since it contains sodium metabisulfite as a preservative.

Its use should be avoided in patients with diagnosed or suspected congenital prolonged QT syndrome or Torsade's de Pointes.

“If these warnings apply to you, even at any time in the past, please consult your doctor.”

Use of ADRENALINE OSEL with food and drink

It has no interaction with food and drinks due to the route of administration.

Pregnancy

Consult your doctor or pharmacist before using this medication.

There are insufficient data on the use of adrenaline in pregnant women. Do not use ADRENALINE OSEL during pregnancy unless considered necessary by your doctor.

Adrenaline crosses the placenta. There are findings regarding a slight increase in the frequency of congenital defects. Adrenaline should not be used during labor. Otherwise, it may prolong the second period of labor.

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

Breast-feeding

No research has been conducted on whether adrenaline can be used safely during breastfeeding.

If you are breastfeeding, you should use it carefully.

Consult your doctor or pharmacist before using this medication.

Driving and using machines

The effects of ADRENALINE OSEL can only be sustained if the drug is administered continuously. Do not drive and use machines unless your organ functions return to normal levels.

Important information about some of the excipients in ADRENALINE OSEL

This medicinal product contains less than 1 mmol (23 mg) sodium per ampoule; that is, it can be considered essentially free of sodium.

Using other medicines

- Tricyclic antidepressants, maprotiline, levodopa, methyldopa, MAO inhibitors, bretyllium, clonidine, dopexamine, entacapone, doxapram, oxytocin, sodium levothyroxine, chlorpheniramine and diphenhydramine may cause arrhythmias and severe hypertension by potentiating the effect of adrenaline.
- Digitalis glycosides and mercury diuretics may increase the arrhythmogenic effect of adrenaline.
- Ergo alkaloids or oxytocin can increase the vasoconstrictor effect.
- If adrenaline or local anesthetics containing adrenaline were used during delivery, uterotonics such as vasopressin, ergonovine, methylergonovine may cause severe hypertensive crises and postpartum brain hemorrhage.
- Beta-adrenergic blockers (propranolol) antagonize the bronchodilator effect of adrenaline.
- Alpha-adrenergic blockers, prazosin, terazosin, haloperidol, loxapine, phenothiazine and thioxanthines can antagonize the vasoconstrictor effect of adrenaline.
- In its halogenated hydrocarbon composition, general anesthetics and cyclopropane increase the arrhythmogenic effect of adrenaline by sensitizing the myocardium.
- Sympathomimetic drugs and phosphodiesterase inhibitors increase the arrhythmogenic effect.
- Beta-adrenergic antagonists reduce the inotropic effect of adrenaline.
- Adrenaline is inactivated in alkaline solutions (sodium bicarbonate, furosemide). It should not be used to treat hypotension caused by droperidol. Blood pressure drops further.
- Herbal medicines containing ephedra and caffeine can intensify the effect of adrenaline. Adrenaline lowers vitamin C and intracellular potassium and magnesium concentrations in plasma.
- When adrenaline is given to patients receiving digoxin, quinidine or fluorohydrocarbons,

these patients have a higher risk of cardiac arrhythmias. Hyperglycemia caused by adrenaline may impair blood sugar control in diabetic patients treated with hypoglycemic drugs. Adrenaline specifically reverses the antihypertensive effects of adrenergic neuron blockers such as guanethidine and has a risk of severe hypertension.

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 ADRENALINE OSEL?

Since ADRENALINE OSEL is administered by your doctor or a healthcare professional, the following section is for your physician or healthcare personnel.

Instructions for use and dose/administration frequency:

Dosage in cases of bronchospasm and hypersensitivity reactions:

The usual starting dose for adults in acute anaphylaxis, severe asthma and allergic reactions is 0.1-0.5 mg (0.1 - 0.5 mL) of ADRENALINE OSEL, administered subcutaneously or intramuscularly. If the cause of the allergy is a drug administered subcutaneously or intramuscularly, ADRENALINE OSEL injection can be administered to the same sites to delay and reduce absorption. Initial doses of ADRENALINE OSEL should be small, these can be increased if necessary. However, the dose administered at one time should not exceed 1 mg.

Subcutaneous doses can be repeated at 10-15-minute intervals in anaphylactic shock. In severe asthma attacks, subcutaneous doses can be repeated at intervals of 20 minutes to 4 hours, depending on the patient's response.

In chronic obstructive pulmonary disease, 0.3 mg (0.3 mL) of adrenaline is given 3 times with 20 minutes intervals and this scheme can be repeated every 2 hours.

In severe anaphylactic shock, the intravenous route should be used to get the drug into the circulation. For this, 0.1-0.2 mg (0.1-0.2 mL) of ADRENALINE OSEL is diluted with 8-10 parts of water for injection and administered slowly by intravenous injection. If necessary, this can be repeated every 5-15 minutes.

Dosage in case of cardiac arrest:

For cardiac reanimation in adults, 0.5-1 mg (0.5-1 mL) of ADRENALINE OSEL is diluted and injected intravenously or intracardiac. Intravenous route is preferred in order not to prevent heart massage. 1-2 mg (1-2 mL) of ADRENALINE OSEL is added to 10 mL of sterile distilled water and instilled into the trachea through the endotracheal tube or 0.3 mg (0.3 mL) of ADRENALINE OSEL is administered subcutaneously after the first intravenous injection or as intravenous infusion at a rate of 1-4 µg / min.

Other administration methods and dosages:

Local hemostatic adrenaline solutions at a concentration of 1: 50.000 (0.002%) - 1: 1.000 (0.1%) are administered to the skin, mucosa and tissue surfaces as wet dressing or spray.

Adrenaline is added to local anesthetic solutions at a ratio of 1: 500.000-1: 50.000. The most commonly used concentration is 1: 200,000.

Method of administration

ADRENALINE OSEL is preferably injected subcutaneously. It can also be performed intramuscularly, but the gluteus muscles should not be used (Anaerobe microorganisms may colonize in the skin of this area and the vasoconstrictor effect of ADRENALINE OSEL can accelerate the formation of *Clostridium welchii* infection by causing hypoxia.).

In emergencies, ADRENALINE OSEL can be diluted and administered as a very slow intravenous injection. In case of cardiac arrest, diluted adrenaline solution can be given by intracardiac injection or endotracheal instillation. Heart massage should also be applied when injected into the heart.

In this way, the drug is provided to participate in the coronary circulation. Adrenaline can be given to an aerosol, vaporizer, IPPB device as oral inhalation.

Adrenaline solutions used for this purpose are more concentrated and injecting them systemically should be avoided. ADRENALINE OSEL can be diluted and applied locally to the skin, mucosa and tissue surfaces. Wet dressing or spray forms are used for this.

Adrenaline dose is expressed by the amount of adrenaline in adrenaline salts.

Different age groups:

Use in children:

Dosage in cases of bronchospasm and hypersensitivity reactions:

In cases of severe asthma and anaphylaxis, ADRENALINE OSEL is given 0.01 mg / kg (0.01 mL/kg) or 0.3 mg/m² (0.3 mL/m²) subcutaneously to children. One-time pediatric dose should not exceed 0.5 mg (0.5 mL). The doses can be repeated at intervals of 20 minutes to 4 hours, depending on the patient's condition and response.

Dosage in case of cardiac arrest:

In children, 0.005-0.01 mg/kg of ADRENALINE OSEL is injected intracardiac or 0.01 mg/kg ADRENALINE OSEL is given intravenously. For this purpose, ready-made ampoules with a concentration of 1: 10.000 should be used. In this way, dilution errors are avoided.

It is not used in children under 2 years of age. It is not recommended for use in children under the age of 12 except in emergencies.

Use in elderly:

The recommended dosage for adults is administered with caution.

Special use cases:

Renal failure:

No data available.

Hepatic failure:

No data available.

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

If you use more ADRENALINE OSEL than you should

Since your medicine will be administered by a healthcare professional, you are not expected to use more ADRENALINE OSEL than you should. However, if you think you have been overdosed, you should inform the healthcare professional as soon as possible. When the dose is exceeded, the following symptoms may occur; cardiac arrhythmias that can result in ventricular fibrillation and death; pulmonary edema and cerebral hemorrhage caused by severe hypertension.

The effects of adrenaline can be overcome with combined alpha and beta-adrenergic blocker drugs such as labetalol or beta-blockers can be used to treat any supraventricular arrhythmia; phentolamine can be used to control alpha-induced effects in the peripheral circulation. Quick-acting nitrates and vasodilators such as sodium nitroprusside may help.

Emergency life support should be provided.

Talk to a doctor or pharmacist if you have used more ADRENALINE OSEL than you should use.

If you forget to use ADRENALINE OSEL

Since your medicine will be administered by a healthcare professional, the dose you need to use is not expected to be forgotten. However, if you think that the dose to be administered may not have been given to you, you should inform the healthcare professional.

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

Effects that may occur when treatment with ADRENALINE OSEL is discontinued

No adverse effects are expected when treatment with ADRENALINE OSEL is terminated.

4. Possible side effects

Other side effects observed with ADRENALINE OSEL are as follows, and the side effects are sorted as shown in the following categories.

Very common: It can be seen in at least 1 in 10 patients.

Common: It can be seen less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: It can be seen less than 1 in 100 patients, but more than 1 in 1000 patients.

Rare: It can be seen less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: It can be seen less than 1 in 10,000 patients.

Unknown : Cannot be estimated from the available data.

Unknown

- Nervousness, anxiety, restlessness, headache, dizziness, lightheadedness, insomnia.
- The appearance or worsening of narrow angle glaucoma, temporary stinging and burning sensations in the eye, eye pain, allergic eyelid reaction, eye irritation.
- Heart palpitations (parenteral), strong heartbeat, facial flushing, pallor of the face, chest pain, increased myocardial (heart muscle) oxygen consumption, heart arrhythmias (irregular heartbeat), sudden death, angina pectoris (locally insufficient heart muscle a discomfort caused by bleeding and often manifested by a feeling of tightness in the middle of the chest), narrowing of the vessels. Ventricular fibrillation (a rhythm disturbance caused by completely irregular and inadequate contractions arising from the ventricles) can be seen and can cause cerebral hemorrhage and pulmonary edema (fluid meeting in the lungs) in patients with severe hypertension (high blood pressure).
- Wheezing, shortness of breath.
- Nausea, vomiting, dry mouth, dry throat.
- Weakness, tremors.
- Acute urinary retention (sudden inability to urinate or a significant amount of residual urine in the bladder after urinating), decreased blood flow to the kidney and internal organs in patients with obstruction at the bladder outlet.

Other

Some biochemical effects such as increased sweating, chills in the arms and legs, local ischemic necrosis (tissue loss due to inability to bleed a region), inhibition of insulin release that can occur

even with low doses and high blood sugar, gluconeogenesis, glycolysis, lipolysis (decomposition of fats), ketogenesis (the release of ketone bodies as a result of the destruction of fatty acids)

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

Reporting of suspected adverse reactions

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 ADRENALINE OSEL

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

Store at room temperature between 15-25°C, protected from light. Do not keep in the refrigerator.

Use in compliance with the expiry date.

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

Do not throw away expired or unused medicines in the trash! Please give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorization Holder and Manufacturer:

OSEL İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Cad. No:52
Beykoz/İSTANBUL/TURKEY

This patient information leaflet approved in 25/10/2022.