

PATIENT INFORMATION LEAFLET

Ephedrine Hydrochloride Osel 0.05 g/1 ml IM/IV/SC Solution for Injection

Sterile

Administered intravenously, intramuscularly or subcutaneously.

- **Active substance:** Each 1 mL ampoule contains 50 mg ephedrine hydrochloride.
- **Excipients:** Sodium chloride and 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. *What EPHEDRINE is and what it is used for?*
2. *What you need to know before you use EPHEDRINE*
3. *How to use EPHEDRINE?*
4. *What are the possible side effects?*
5. *How to store EPHEDRINE*

Headings are included.

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

- EPHEDRINE is presented as an ampoule containing solution **for injection for intramuscular, intravenous or subcutaneous administration** whose active ingredient is ephedrine hydrochloride.
- EPHEDRINE is included in the drug group called “adrenergic and dopaminergic drugs” used in the treatment of low blood pressure (hypotension).
- Each box contains 10 or 100 pcs of 1 ml amber colored ampoules.

EPHEDRINE is used in the following situations:

- Prevention and treatment of low blood pressure seen during general or local-regional anesthesia, with or without a decrease in heart rate;
- It is used in the symptomatic treatment of severe acute bronchospasm (narrowing of the bronchi)

seen in respiratory tract diseases such as bronchial asthma.

- EPHEDRINE can also be used in the treatment of other diseases such as shock and arrhythmia (heartbeat irregularity).

If you have questions about how EPHEDRINE works or why it was given to you, please consult to your doctor.

2. What you need to know before you use EPHEDRINE

DO NOT USE EPHEDRINE;

If;

- You have hypersensitivity (allergy) to ephedrine hydrochloride or other sympathomimetic drugs (drug group including ephedrine) or any of the excipients in EPHEDRINE
- You have mental disorder (psychoneurosis), hyperexcitability, adrenal gland tumor (pheochromocytoma) that causes your blood pressure to rise, arteriosclerosis or aneurysm (regional swelling in the vein, ballooning)
- You are taking other indirect sympathomimetic drugs such as phenylpropanolamine, phenylephrine, pseudoephedrine, methylphenidate
- You are taking medicines such as selegiline (used in the treatment of Parkinson's disease), moclobemide (used to treat depression) and linezolid (antibiotics), which are included in the group of MAO (monoamine oxidase) inhibitors, or have used them in the last 14 days
- You have a disease called "narrow angle glaucoma" that causes a sudden increase in the pressure in your eye.
- You have received cyclopropane or halogenated hydrocarbon derivative anesthetics in general anesthesia
- Generally, in cases where vasopressor (blood pressure increasing) drugs should not be used [eg; EPHEDRINE should not be used in patients with thyrotoxicosis (disease due to excessive increase of thyroid hormones in the blood), diabetes, blood pressure greater than 130/80 mmHg in pregnant patients, hypertension (high blood pressure) or cardiovascular diseases.

USE EPHEDRINE CAREFULLY;

Caution should be exercised in the following situations:

- Hypovolemia (decrease in blood volume)
- Hypoxia (oxygen deficiency in tissues), hypercapnia (excessive carbon dioxide in the blood), acidosis (excessive acid accumulation in the blood)
- Prostate hypertrophy (prostate enlargement)
- You have a family history of known heart disease or long QT syndrome (a condition in the heart that can lead to serious arrhythmias and sudden death)

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

In addition, EPHEDRINE should not be used in children under 2 years of age unless it is absolutely necessary.

Warning for athletes:

This medicinal product contains an active substance that causes a positive result in doping control tests.

Use of EPHEDRINE with food and drink

Not applicable.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

It has been reported that EPHEDRINE administered during birth increases the heart rate of the unborn baby.

If the mother's blood pressure is over 130/80 mmHg during pregnancy, EPHEDRINE should not be used. It is not known whether EPHEDRINE is safe to use during pregnancy. For this reason, do not use EPHEDRINE during pregnancy unless your doctor recommends it.

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

Breast-feeding

Consult your doctor or pharmacist before using this medication.

It is known that EPHEDRINE passes into breast milk. For this reason, do not use EPHEDRINE during breastfeeding unless your doctor recommends it.

Driving and using machines

EPHEDRINE may have an effect on the drive and use of machines. Consult your doctor before driving or using machine.

Important information about some excipients found in the composition of EPHEDRINE

If you do not have any hypersensitivity to the excipients in EPHEDRINE, no negative effects are expected due to these excipients.

Use with other medicines

Please inform your doctor if you plan to take, are taking or have recently taken any other medicines, including non-prescription medicines, vaccines and herbal medicines.

EPHEDRINE should not be used with the following drugs:

- Drugs such as phenelzine or moclobemide used to treat severe depression [These drugs are known

as MAO (monoamine oxidase) inhibitors]. Do not use EPHEDRINE if you are using these medicines or if two weeks have not yet passed although you have stopped.

- Medicines to treat high blood pressure (eg, reserpine, methyldopa, guanetidine, clonidine)
- Theophylline and its derivatives used in the treatment of respiratory tract diseases
- Some medicines with vascular constricting effects, used in migraine headaches or during childbirth (e.g. ergotamine, ergometrine, methylethergometrine, oxytocin)
- Medicines effective against depression/mental breakdown such as tricyclic antidepressants (eg imipramine) and serotonergic-noradrenergic antidepressants (eg mianserin, venlafaxine)

Other drugs that may interact with EPHEDRINE are listed below:

- Atropine sulfate used in slow heartbeat, hypotension and heart rhythm disorder
- Medicines that strengthen the heart muscle (eg digoxin) known as cardiac glycosides
- Diuretic drugs (eg furosemide)
- Medicines that make urine more basic (eg acetazolamide, dichlorphenamide, sodium bicarbonate and sodium citrate)
- Methylphenidate [Used in the treatment of "Attention Deficit Hyperactivity Disorder (ADHD)"]
- Indirect sympathetic nervous system inhibitors such as phenylpropyl amine or pseudoephedrine drugs used to treat nasal congestion)
- Phenylephrine (a drug used to treat low blood pressure)
- Drugs that act by directly stimulating alpha receptors in the sympathetic nervous system (used in the treatment of low blood pressure and nasal congestion in the mouth and/or nose)
- Anesthetic drugs used by inhalation, such as halothane
- Sibutramine (a drug used as an appetite suppressant)
- Linezolid (a drug used to treat infections)
- Corticosteroids (It is a type of drug used in the treatment of inflammation in many diseases and allergic conditions)
- Medicines used in the treatment of epilepsy
- Doxapram (It is a drug used in respiratory problems)
- Oxytocin (a drug used during childbirth)

Special precautions should be taken if these drugs that may interact with EPHEDRINE are to be used together.

If you are using or have recently used any type of prescription or non-prescription drugs, please

inform your physician or your pharmacist.

3. How to use EPHEDRINE

EPHEDRINE will be administered to you by your doctor or a nurse.

Instructions for appropriate use and dose/administration frequency:

Your doctor will determine the dose of your medicine depending on your illness and will administer it to you.

Method of administration:

EPHEDRINE is administered intravenously, intramuscularly or subcutaneously.

Various age groups

Use in Children:

Your doctor will determine the dose of the drug based on your child's weight or height and administer it to your child.

Use in Elderly:

EPHEDRINE should be administered with caution in elderly patients, especially men with prostate disease.

Special use cases:

Kidney/Liver failure:

If you have liver or kidney problems, use this drug product carefully.

Talk to your doctor or pharmacist if you have the impression that the effect of EPHEDRINE is too strong or weak.

If you have used more EPHEDRINE than you should

Since this medicine is administered to you by your doctor or nurse, it is unlikely that you will use too much EPHEDRINE. However, in excessive doses, migraine, nausea, vomiting, high blood pressure, accelerated heartbeat, fever, mental disorders, imagination, heart rhythm disorders, respiratory difficulties, convulsion and coma can be observed. If you think you have any of these symptoms, tell your doctor immediately.

If you have used more than you should use from EPHEDRINE, talk to a doctor or pharmacist.

If you forget to use EPHEDRINE

Do not administer a double dose to make up for forgotten doses.

Effects that may occur when treatment with EPHEDRINE is concluded

Low blood pressure (hypotension) may recur when the medication is stopped. Carefully follow the instructions your doctor recommends to you.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in EPHEDRINE.

If you experience any of the following side effects, stop using the drug immediately and contact your doctor for immediate assistance:

- Difficulty in breathing
- Abnormal heart rhythm
- Palpitations in the heart, working faster than normal, increased blood pressure or pain in the heart area, decreased heart rate, low blood pressure
- Heart failure (cardiac arrest)
- Cerebral hemorrhage
- Fluid accumulation in the lungs (pulmonary edema)
- Increase in intraocular pressure (glaucoma)
- Difficulty urinating

Side effects are listed as shown in the categories below.

Very common	: It can be seen in at least 1 of 10 patients.
Common	: Less than one in 10 patients, but more than one in 100 patients.
Not Common	: Less than one in 100 patients, but more than one in 1000 patients.
Rare	: Less than one in 1000 patients but more than one in 10,000 patients.
Very rare	: Less than one in 10,000 patients can be seen.
Unknown	: Cannot be estimated from the available data.

Common:

- Unconsciousness, feeling anxious (anxiety), depression
- Nervousness, easy excitability, restlessness, weakness, sleep problems, headache, sweating
- Shortness of breath
- Nausea, vomiting

Unknown:

- Problems associated with blood clotting
- Allergy (hypersensitivity)
- Changes in personality or how you feel or think about yourself, fears, dizziness

- Shivering, excessive salivation
- Decreased appetite
- Low levels of potassium in the blood or changes in your blood sugar levels

All these are serious side effects. Emergency medical attention may be required. If you notice any of these symptoms, tell your doctor immediately.

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

Keep EPHEDRINE out of the sight and reach of children, and in its packaging.

Store at room temperature between 15-30 °C, protect from light.

Use in compliance with the expiry date.

Do not use EPHEDRINE after the expiration date stated on the packaging.

Do not throw away expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder and Manufacturing Site:

OSEL İlaç San. ve Tic. A.Ş.

Akbaba Mah. Maraş Caddesi No:52

34820 Beykoz/İSTANBUL

This patient information leaflet was approved on 05/10/2017.

FOLLOWING INFORMATION IS FOR HEALTH PROFESSIONAL TO ADMINISTER THIS MEDICINAL PRODUCT

Posology/administration frequency and duration:

In adults:

As a pressor agent in the treatment of hypotension:

EPHEDRINE should be administered as soon as possible and at the lowest effective dose.

- Subcutaneous or intramuscular administration: 25 - 50 mg, if necessary, up to a maximum 150 mg in 24 hours.

Intravenous administration: 10 - 25 mg (as slow injection), if necessary, can be repeated after 10 minutes, the maximum daily dose should not exceed 150 mg.

During treatment with a pressor agent, blood pressure should be raised slightly below the patient's normal blood pressure. In patients who were previously normotensive, systolic blood pressure should be kept at the level of 80-100 mmHg. The systolic blood pressure of patients who were previously hypertensive should be kept 30-40 mmHg below the patient's normal blood pressure. In patients with severe hypotension, even lower blood pressure may be desirable if blood or fluid replacement therapies are not completed.

In the treatment of severe acute bronchospasms:

- The lowest effective dose should be administered intravenously (slowly): 12.5 - 25 mg, additional doses should be decided according to the patient's response.

Method of administration:

EPHEDRINE can be administered subcutaneously, intramuscularly and intravenously. The route of administration is determined according to individual needs.

IV administration should be preferred in emergency situations that require immediate response. IV administration is preferred to overcome the absorption phase in patients with shock. In IV administrations, the injection should be given slowly.

Care must be taken to avoid extravasation; otherwise, tissue necrosis and skin shedding may occur.

EPHEDRINE should be administered at the lowest effective dose.

The maximum daily dose = 150 mg should not be exceeded.

Additional information on special populations:

• Pediatric population:

In children, daily doses of 3 mg/kg or 100 mg/m² can be administered subcutaneously or IV in 4-6 equal doses.

It should not be used in children under the age of 2 unless absolutely necessary.

• **Geriatric population:**

Since EPHEDRINE causes acute urinary retention, it should be administered with caution in elderly patients, especially those with prostatic hypertrophy.

Monitoring:

Cardiovascular parameters such as blood pressure, ECG, cardiac output, central venous pressure and pulmonary artery pressure should be monitored during EPHEDRINE treatment. Urine output should be monitored separately.

Drug abuse and misuse:

Due to the stimulating effects of ephedrine, misuse and abuse by young adults, bodybuilders and other athletes have been reported.

Food supplements containing ephedrine alkaloids have been associated with serious cardiac adverse effects (eg hypertension possibly resulting in MI, stroke or death), CNS effects, and death. These aspects should be taken into account in the prescription and storage of the drug.

Psychological and psychic dependence may occur due to the use of ephedrine.

Athletes:

Athletes should be warned that this medicinal product contains a drug substance that causes a positive reaction in doping control tests.

Overdose and treatment

Symptoms:

In excessive doses, migraine, nausea, vomiting, hypertension, tachycardia, fever, paranoid psychosis, hallucinations, ventricular and supraventricular rhythm disturbances, respiratory depression, convulsion and coma may be seen.

The lethal dose in humans is about 2 g and corresponds to blood concentrations of 3.5 - 20 mg/L.

Treatment:

Intensive supportive therapy may be required in case of drug-induced ephedrine overdose. For the treatment of supraventricular tachycardia, 50-200 mg labetalol can be administered by slow intravenous injection under electrocardiographic monitoring.

The development of marked hypokalemia ($< 2.8 \text{ mmol.L}^{-1}$) due to potassium displacement between body compartments increases susceptibility to cardiac arrhythmias and can be treated by infusion of potassium chloride in addition to propranolol and correction of respiratory alkalosis, if present.

A benzodiazepine and/or neuroleptic agent may be required for stimulating effects in the central nervous system. Treatment options for severe hypertension include intravenously administered nitrates, calcium channel blockers, sodium nitroprusside, labetalol, or phentolamine. The choice of antihypertensive drug depends on the accompanying conditions in the patient, the clinical condition of the patient and which drug is available in the clinic.