

PATIENT INFORMATION LEAFLET

Osetron 4 mg/2 mL I.V./I.M. ampoule containing solution for injection

Administered by intramuscularly or intravenously.

Sterile

Active Ingredient: Contains 4 mg ondansetron (as hydrochloride dihydrate) in each ampoule (2 mL)

Excipients: Citric acid monohydrate, sodium citrate, sodium chloride, sodium hydroxide 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 OSETRON is and what it is used for?***
- 2. What you need to know before you use OSETRON***
- 3. How to use OSETRON?***
- 4. Possible side effects***
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1. What OSETRON is and what it is used for?

OSETRON contains ondansetron active ingredient. It is in ampoules each contains particle free, clear, colorless and odorless solution for injection and infusion.

OSETRON belongs to a group of medicines called anti-emetics. Some medications (e.g., cancer medications) may cause you to feel sick and vomit. OSETRON prevents you from feeling sick or vomiting. OSETRON is used to prevent nausea and vomiting associated with cancer treatments with drugs and radiation. It is also used to prevent nausea and vomiting after surgeries.

Your doctor has chosen this drug according to you and your condition.

OSETRON is given to prevent you from feeling sick and vomiting after treatment.

2. What you need to know before you use OSETRON

DO NOT USE OSETRON

If;

- You are allergic to Ondansetron or any of the other substances in the OSETRON content.
- You are taking medication containing apomorphine hydrochloride (used to treat Parkinson's)

Use OSETRON CAREFULLY if;

- You are hypersensitive (allergic) to other selective 5-HT₃ receptor antagonists (a group of drugs that prevent nausea and vomiting), such as granisetron
- You have complaints of intestinal obstruction or severe constipation
- You have liver disease
- You have heart problems that include irregular heartbeat (arrhythmia) or heart failure (difficulty breathing and swelling of the feet)
- You have congestive heart failure (a combination of right and left heart failure)
- You have a disease of slowing the heartbeat (bradyarrhythmia)
- You have congenital long QT syndrome, which can cause sudden death and is a genetic disease
- You are taking other drugs that increase the level of the hormone serotonin
- You have had tonsil or nasal flesh surgery
- There are abnormalities in electrolyte tests such as sodium, potassium, magnesium in your blood.
- The use of OSETRON after tonsil and adenoid surgery may mask hidden bleeding. In such a case, your doctor will follow you carefully.
- Symptoms such as restlessness, confusion, sweating, increased reflexes, muscle spasm, tremor, and increased heart rate may occur after use with serotonergic drugs that increase the substance called serotonin in the body. If OSETRON is used with these drugs, your doctor will follow you closely.
- Children under the age of 18 who use OSETRON in combination with liver-damaging chemotherapy drugs will be closely monitored for impaired liver function.

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

Use of OSETRON with food and drink

No data available.

Pregnancy

Consult your doctor or pharmacist before using this medication.

Do not use OSETRON in the first trimester of your pregnancy. OSETRON may increase the risk of your baby being born with a cleft lip and/or a cleft palate (openings or crevices in the upper lip and/or the top of the mouth). Before using OSETRON, consult your doctor or pharmacist if you are pregnant, you think you are pregnant, or planning to have a baby.

It is advisable to use an effective method of contraception if you are a woman who has the potential to give birth to children.

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.

Do not use OSETRON when breast-feeding. It is not known whether OSETRON passes into breast milk.

Driving and using machines

It is not likely to have any effect.

Important information about some of the excipients in OSETRON

This medicinal product contains less than 1 mmol sodium (23 mg) per dose; however, no adverse side effects are expected for this dose.

Other medicines and OSETRON

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This is because OSETRON can affect the way some medicines work. Also, some other medicines can affect the way OSETRON works.

Tell your doctor, nurse, or pharmacist, especially if you are taking any of the following medications:

- You should not use OSETRON if you are taking apomorphine, which is used to treat Parkinson's disease. This condition can cause loss of consciousness and drop in blood pressure.
- carbamazepine or phenytoin used to treat sara,
- rifampicin used in the treatment of infections such as tuberculosis,
- fungicides such as erythromycin and ketoconazole,
- anti-arrhythmic drugs that treat irregular heartbeat,
- beta-blocker drugs such as bisoprolol, carvedilol, metoprolol, nebivolol, pindolol and timolol, which are used to treat certain heart and eye problems, anxiety and prevent migraine,
- tramadol which is a painkiller,

- drugs that affect the heart (such as haloperidol or methadone),
- cancer drugs (especially anthracyclines and trastuzumab),
- SSRIs (selective serotonin reuptake inhibitors), including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, used in the treatment of depression and/or anxiety,
- SNRIs (serotonin noradrenaline reuptake inhibitors), such as venlafaxine, duloxetine, used to treat depression and/or anxiety,

If you are not sure if any of the above valid for you, talk to your doctor, nurse or pharmacist before you start taking OSETRON.

Please inform your doctor or pharmacist if you are currently using any prescription or non-prescription medication or if you have recently used it.

3. How to use OSETRON

Instructions for proper use and dosage / administration frequency:

Depending on your condition, your physician will determine the dose of your medicine and administer it to you.

Use in Adults:

At repeated doses in all adult patients (including the elderly):

Repeated intravenous doses of ondansetron should be administered at least 4 hours apart.

Adult patients younger than 75 years:

For the prevention of chemotherapy-induced nausea and vomiting in adults (less than 75 years of age), a single intravenous dose of ondansetron should not exceed 16 mg (infused over at least 15 minutes).

Method of administration

Administered by intramuscularly or by intravenously.

Different age groups:

Use in children and adolescents:

Vomiting after chemotherapy and radiotherapy (from 6 months to 17 years):

The physician will determine the dose of the drug product depending on condition and administer it to your child.

Postoperative nausea and vomiting:

The physician will determine the dose of the drug product depending on condition and administer it to your child.

Use in the elderly:

Preparation and application of dilution in elderly patients aged 65 and over:

All intravenous doses should be diluted in 50-100 mL of saline or other compatible liquid and infused over at least 15 minutes.

Elderly patients 75 years and older:

For the prevention of chemotherapy-induced nausea and vomiting, a single intravenous dose of ondansetron should not exceed 8 mg (infused over at least 15 minutes).

Special cases for use:**Renal failure:**

For renal failure there is no need for changing the dose, frequency and route of administration of OSETRON.

Liver failure:

In patients with moderate or severe liver dysfunction, the total daily dose of OSETRON should not exceed 8 mg.

If you have an impression that the effect of OSETRON is too strong or too weak, consult to your physician or pharmacist.

If you use more OSETRON than you should

Consult to a physician or pharmacist if you have used more OSETRON than you should use.

If you forget to use OSETRON

Do not use a double dose to make up for a forgotten dose.

Side effects after concluding treatment with OSETRON

Your doctor will administer OSETRON to you during the period of treatment.

4. Possible side effects

Like all medicines, OSETRON may have side effects in people who are sensitive to substances in its content.

This drug product did not cause any problems in the majority of patients who used this medicine.

If you have any of the following, stop using OSETRON and IMMEDIATELY tell your doctor or contact the emergency department of your nearest hospital:

- Hypersensitivity reactions. Symptoms;
 - Sudden snarls and jaw pain or jaw tension.
 - Swelling of the eyelids, face, lips, mouth or tongue.
 - Tuberous skin rash or urticaria anywhere in the body.
 - Sudden circulatory failure (collapse).

These are all very serious side effects.

If you have one of these, you have a serious allergy to OSETRON. You may need immediate medical attention or hospitalization.

Other side effects are classified as shown in the following categories:

Very common	: Can be seen in at least one of 10 patients.
Common	: Less than one in 10 patients, but more than one in 100 patients.
Uncommon	: Less than one in 100 patients, but more than one in 1,000 patients.
Rare	: Less than one in 1,000 patients, but more than one in 10,000 patients.
Very rare	: less than one in 10,000 patients.
Unknown	: cannot be estimated from the data available.

Very common

- Headache

Common

- Fever or feeling hot flashes
- Constipation
- If you are taking it with a drug called cisplatin, there may be changes in your tests that show liver function, otherwise it is a non-common side effect.
- Reaction in the application area

Uncommon

- Hiccups
- Low blood pressure, asthenia
- Slow or irregular heart beats
- Chest pain
- Seizures
- Normal movements or swaying in the body
- Change in tests showing liver function

Rare

- Dizziness or lightheadedness
- Blurred vision
- Heart rhythm deterioration (sometimes can cause sudden loss of consciousness.)

Very rare

- Decreased vision or general vision loss of temporary vision in 20 minutes
- Toxic (poisonous) skin rash, toxic (poisonous) epidermal necrolysis (injured rash on the upper layer of the skin)

If you encounter any side effects not mentioned in this patient information leaflet, please inform 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 OSETRON

Keep OSETRON out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

The prepared solution should be used immediately.

Use in accordance with the expiry date.

Do not use OSETRON after the expiry date which is stated on the package.

Do not throw away expired or unused medicines! Give it to the collection system determined by your country's relevant authority.

Marketing Authorization Holder:

HAYER FARMA İlaç A.Ş.
Akbaba Mahallesi Maraş Cad. No: 52/2/1
Beykoz / İstanbul

Manufacturing Site:

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

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