

PATIENT INFORMATION LEAFLET

VOTRON 250 µg/5 mL vial containing IV injection of solution

Sterile, apyrogen

For intravenous usage.

- **Active ingredient:**

Palonosetrone (as hydrochloride).

5 ml vial containing 250 microgram palonosterone (Each of ml solution contains 50 microgram palonosetrone).

- **Excipients:**

Mannitole, trisodium citrate, citric acide monohydrate, water for injections, solution of sodium hydroxide and solution of hydrochloric acide.

Before using this medicine, please read this patient information leaflet carefully, because it contains important information for you.

**Save this patient information leaflet. You may need to read it again later.*

**If you have additional questions, please consult your doctor or pharmacist.*

**This medicine is prescribed for you individually, do not pass it on to others.*

**Please inform your doctor about the usage of this medicine when you go to a hospital or a doctor during the usage of this medicine.*

Please follow this patient information leaflet exactly. Except recommended dosage for you, do not use **high or **low** doses.*

In this patient information leaflet:

- 1. What is VOTRON and what is it used for?**
- 2. Precautions before using of VOTRON,**
- 3. How to use VOTRON?**
- 4. What are possible side effects?**
- 5. Storage of VOTRON Heads are available.**

- 1. What is VOTRON and what is used for?**

- VOTRON is a colorless solution administered intravenously
- VOTRON is included in the medicine group known as serotonin antagonists (5-HT₃).
- Medicines in this groups show their effects by stopping serotonin that causes nausea and vomiting.
- VOTRON is packaged in 5 ml vials containing 5 ml solution. Each vial contains one dosage.
- VOTRON is used to prevent nausea and vomiting related to treatment of cancer with medicines (chemotherapy).

2. Precautions before usage of VOTRON

Do not use VOTRON for following situations:

If you are hyper-sensitive (allergic) to palonosetron or other excipients of VOTRON (refer to list of excipients).

Use VOTRON carefully in following situations:

If;

- You have acute obstruction of large intestine or repeated constipation history,
- You are taking VOTRON with other medicines like amiodarone, nifedipine, domperidone, kinidin, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, which can cause abnormal cardiac rhythms,
- You have individual or family history of heart rhythm variance,
- Other heart diseases,
- You have instability of minerals in your blood like potassium or magnesium,

If you are not taking another kind of chemotherapy medicines, using VOTRON in the following days is not recommended.

If these precautions are valid also in the past, please consult your doctor.

Using VOTRON with food and drinks:

With regard to application route, there is no interaction with food and drinks.

Pregnancy

Before using this medicine, consult your doctor or pharmacist.

If you are pregnant or you think you are, your doctor will not administer VOTRON to you if there is no necessity.

There is not enough data related to any harm due to usage of VOTRON in pregnant women.

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

Lactation

Before using this medicine, please consult your doctor.

It is not known whether VOTRON excreted to mother milk or not.

If you are breast feeding consult your doctor or pharmacist before using VOTRON.

Driving and machinery usage

Palonosetron can cause prostration or dizziness. If you feel one of these do not drive or use machinery.

Important information about excipients of VOTRON:

If you do not have hyper-sensitivity to constituents in VOTRON, negative effects are not expected related to these substances.

This medical product contains less than 1 mmol (23mg) sodium; so it basically does not contain sodium.

Usage of other medicines:

Inform your doctor or pharmacist if you are taking, have taken in a short time or will take any of the medicines below.

- SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, used in the treatment of depression and/or anxiety disorder
- SNRIs (selective noradrenaline reuptake inhibitors) including venlafaxine, duloxetine used in the treatment of depression and/or anxiety disorder.

If you are currently using or have recently used any prescription or over-the-counter drug, inform your doctor or pharmacist of these drugs.

3. How to use VOTRON?

Instructions for suitable usage and dosage/administration frequency:

VOTRON is administered intravenously by your doctor or nurse approximately 30 minutes before starting chemotherapy.

Administration method and route:

- Use by intravenous injection.
- Your doctor or nurse will inject VOTRON approximately 30 minutes before starting chemotherapy.
- 250 microgram VOTRON is given and by intravenously by rapid injection. Remaining parts from opened vial must be discarded.

Different age groups: Usage in children:

Usage of VOTRON is not recommended for children.

Usage in geriatric patients:

Dosage arrangement is not necessary for geriatrics and used at recommended dosage by your doctor.

Special usage conditions: Renal/liver insufficiencies:

In patients with renal function insufficiency, special dose arrangement is not necessary except for recommended dosage of your doctor. For patients under hemodialysis with advanced stage of

renal disease, there is not enough data, so, please consult your doctor.

Patients with liver insufficiency, dose arrangement is not necessary except for recommended dosage by your doctor.

Follow these instructions unless your doctor recommends otherwise. Take your medicine on time.

Your doctor will inform you about the timelines of treatment with VOTRON. Do not stop treatment early, because otherwise you will not be able to receive expected results.

If you notice that effects of VOTRON is too strong or too weak, please speak with your doctor or pharmacist.

If you have used more than required dosage of VOTRON:

If you have used VOTRON too much from recommended dosage, speak to your doctor or pharmacist.

If you have forgotten to take VOTRON:

Your doctor will decide the time of next dose.

It is important to follow instructions of your doctor about new administration time of next dose.

Do not take double dose to balance the forgotten dose.

Possible effects occurred after finishing treatment with VOTRON:

There are no effects.

4. What is possible side effects?

Like all other medicines, side effects can be seen in people who are sensitive to constituents of VOTRON.

If you notice one of the followings, please stop using VOTRON and IMMEDIATELY inform your doctor or go to an emergency service of the nearest hospital :

- Inflation in the lips, face, tongue and throat, trouble in breathing or fainting, rash or itch.

These are all very serious side effects. If you feel any of them, you are seriously allergic to VOTRON. Emergency medical treatment or hospital care can be required.

All of these very serious side effects are seen very rarely.

Side effects are categorised 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.

Uncommon: Less than one in 100 patients, but more than one in 1000 patients.

Rare: Less than one in 1,000 patients, but more than one in 10,000 patients

visible.

Very rare: less than one in 10,000 patients.

Unknown: Unable to predict based on available data. Common side effects:

- Headache
- Dizziness
- Constipation
- Diarrhea

Non-common side effects:

- High or low blood pressure
- Abnormal heart rhythm or decrease in blood flow to heart
- Change of vein colors or widening veins.
- Too low or too high levels of potassium in blood.
- High levels of sugar in blood or urine
- Low levels of calcium in blood
- High levels of bilirubin that makes coloring in blood
- High levels of some liver enzymes
- Over happiness or anxiety
- Sleepiness or sleeping problems
- Loss of appetite or poor appetite
- Asthenia, prostration, fever or flu like symptoms
- Insensibility, burning, tingling or whimpering in tissue
- Itchy skin rash
- Vision failure or eye scratchiness
- Motion sickness
- Ringing in the ears
- Hiccups, flatulence, dry mouth, indigestion
- Stomach-ache
- Trouble in urinate
- Muscle-ache
- Electrocardiogram anomalies (QT prolongation) Very rare side effects:

Allergic reactions to VOTRON (Inflation in the lips, face, tongue and throat, trouble in breathing or fainting, rash or itch.)

Burning or pain at injection area

Reporting of side effects

If you feel any side effects not listed in this leaflet speak to a doctor, pharmacist or nurse. Furthermore report the side effects you feel by clicking “Reporting Medicine Side Effect” in www.titck.gov.tr or by calling 0 800 314 00 08 side effect report line Turkey Pharmacovigilance Center. By reporting side effects, you can help provide more information on the safety of this medicine

If you notice other side effects which are not described in this patient information leaflet, inform your doctor or pharmacist.

5. Storage of VOTRON:

Store VOTRON at places where children can not see or reach.

Store VOTRON below 25°C at room temperature protecting from light and humidity.

Do not freeze VOTRON. If medicine is frozen, do not dissolve and use. For single usage only.

Remaining solution from vial must be discarded. **Use compatibly with its expiry date.**

Do not use VOTRON after the expiry date written on the package.

If you notice any deterioration on the product and/or packaging, do not use VOTRON.

Registration holder: Biem İlaç San. ve Tic. A.Ş.

Anıttepe Mah. Turgut Reis Cad. No:21

Tandoğan / Çankaya - Ankara

Manufacturing site: İDOL İLAÇ DOLUM SAN. ve TİC. A.Ş.

Davutpaşa Cad. CebeAli Bey Sok.No:20

Zeytinburnu / İSTANBUL

This patient information leaflet is approved on 30/07/2015.