

## PACKAGE LEAFLET

### VONAXI 250 mcg/5 ml I.V. Solution for Injection, Vial

Administered intravenously.

#### Sterile

- **Active Substance:** Each vial contains 280 micrograms of palonosetron hydrochloride equivalent to 250 micrograms of palonosetron as the active substance. Each ml of solution contains 56.2 micrograms palonosetron hydrochloride equivalent to 50 micrograms palonosetron.
- **Excipient(s):** Mannitol (E 421), disodium edetate, sodium citrate, citric acid monohydrate, water for injection, sodium hydroxide solution and hydrochloric acid solution.

**Please read this entire leaflet carefully before you start having this medicine, because it contains important information for you.**

- *Keep this package 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.*
- *While you are using this drug, if you go to a doctor or a hospital please tell your doctor that you are taking this medicine.*
- *Follow the instructions, written in this leaflet, exactly. Do not use **higher or lower** doses other than the recommended dose to you.*

#### **This leaflet includes following topics:**

- 1. What VONAXI is and what it is used for?*
- 2. Before you use VONAXI*
- 3. How to use VONAXI?*
- 4. Possible side effects*
- 5. How to store VONAXI?*

#### **1. What VONAXI is and what it is used for?**

VONAXI is a colorless solution administered intravenously. It belongs to a group of medicines called ‘serotonin (5HT<sub>3</sub>) antagonists’.

VONAXI is packaged in a glass vial containing 5 ml of solution. Each vial contains a single dose.

VONAXI is used to prevent nausea and vomiting associated with cancer treatments (chemotherapy).

## **2. Before you use VONAXI**

### **Do not use VONAXI in following cases:**

If you are hypersensitive (allergic) to VONAXI or any of the other ingredients of VONAXI (see list of excipients).

### **Take special care with VONAXI in the following cases,**

If,

- You had acute large-bowel obstruction or repeated constipation in the past,
- You are taking VONAXI with other drugs that may cause arrhythmia.

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

### **Use of VONAXI with food and beverage**

Due to the application method, there is no interaction with food and beverages.

### **Pregnancy**

*Before using the drug consult your doctor or pharmacist.*

There is not enough data on the use of VONAXI in pregnant women. VONAXI should not be used in pregnant women unless doctor decides that it is necessary.

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

### **Breast-feeding**

*Before using the drug, consult your doctor or pharmacist.*

Since it is not known whether VONAXI is excreted in breast milk, if the use of the drug is mandatory, breast-feeding should be discontinued during the treatment.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

Since palonosetron may induce dizziness, somnolence or fatigue, patients should be cautioned when driving or operating machines.

### **Important information about some excipients in the content of VONAXI**

If you do not have hypersensitivity to the excipients of VONAXI, no side effects from these substances are to be expected.

VONAXI contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially 'sodium- free'.

### **Use with other medicines**

There is no harm in the concomitant use of VONAXI with other drugs.

*If you are using presently or have used recently any prescribed or non-prescribed medicine, please give information to your doctor or pharmacist.*

### **3. How to use VONAXI**

#### **Instructions for appropriate usage and dose / frequency of application:**

VONAXI is administered by your doctor or nurse by intravenous injection as a single dose about 30 minutes before the start of chemotherapy.

#### **Administration route and method:**

- It is given as an injection into a vein.
- VONAXI is normally given by a doctor or nurse about 30 minutes before the start of chemotherapy.
- 250 micrograms of VONAXI is administered intravenously with rapid injection. Discard any unused solution.

#### **Different Age Groups:**

##### **Children:**

VONAXI is not recommended to be used in patients below the age of 18 years.

##### **Elderly:**

It is used according to the dose recommended by the doctor, dose adjustment is not necessary for the elderly.

**Additional information on special populations:**

**Hepatic/Renal impairment:**

In patients with impaired renal function, a specific dose adjustment is not required except for the dose recommended by the physician. Please consult your doctor as there is no data available for end stage renal disease undergoing haemodialysis.

In patients with hepatic dysfunction, no special dose adjustment is required except for the dose recommended by the physician.

Unless your doctor recommends otherwise follow these instructions.

Do not forget to take the medicine in time.

Your doctor will inform you about VONAXI treatment period. Do not discontinue the treatment early because you cannot get the desired result.

*If you have feeling that effect of VONAXI is too strong or too weak, talk to your doctor or pharmacist.*

**If you have more VONAXI than you should:**

*If you have more VONAXI than you should, talk to a doctor or a pharmacist.*

**If you forget to use VONAXI**

Your doctor will decide when the forgotten dose will be administered.

It is important to follow your doctor's instructions for the new administration time of the following dose.

*Do not take double dose to make up for a forgotten dose.*

**Effects that may arise after termination of treatment with VONAXI**

Not applicable.

**4. Possible side effects**

Like all medicines, side effects may occur in patients who are sensitive to the ingredients present in VONAXI.

**If any of the following occurs, stop using VONAXI and report it to your doctor IMMEDIATELY or contact your nearest hospital emergency department:**

- Rash
- Flush

These are all very serious side effects. If one of these exists in you, then you have a serious allergy against VONAXI. You may need urgent medical attention or hospitalized.

All of these very serious side effects are very rare.

**If you notice any of the followings, tell your doctor immediately or contact the emergency department of your nearest hospital.**

- Abnormal heart rate or lack of blood flow to the heart,
- Abnormal heart rate or lack of blood flow to the heart
- High fever
- Difficulty passing water (urinating),
- Change in the color of the vein.

All these are serious side effects. Immediate medical attention may be required.

Serious side effects are very rare.

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

- Motion sickness
- Ringing in the ear
- Impaired vision
- Diarrhea
- Abdominal pain
- Dry mouth
- Hiccups
- Indigestion
- Weakness
- Feeling tired
- Decrease of appetite

- Headache
- Change in sleep pattern; for instance sleeplessness or excessive sleepiness
- Flu
- Increased irritability
- Joint pain
- Water retention in the body (edema)

These are mild side effects of VONAXI.

*If you experience any side effects not mentioned in this package leaflet, please inform your doctor or pharmacist.*

### **Reporting of side effects**

If you get any side effects, which are mentioned or not mentioned in Package Insert, talk to your doctor, pharmacist or nurse. Moreover, report side effects that you have experienced to Turkey Pharmacovigilance Center (TÜFAM) by clicking icon “Reporting Side Effects” on the website [www.titck.gov.tr](http://www.titck.gov.tr) or by calling 0 800 314 00 08, which is the line of Reporting Side Effects”. By reporting side effects, you will contribute to learn more about the safety of the medicine you are using.

### **5. How to Store VONAXI**

*Keep VONAXI out of reach and sight of children and in the original package.*

VONAXI should be stored at room temperatures below 25°C, by protecting from light and moisture.

Do not freeze VONAXI. If the product is frozen, it should not be used after dissolving.

Single use only, any unused solution should be discarded.

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

*Do not use VONAXI after the expiration date on package.*

If you notice defects in the product and/or its package, do not use VONAXI.

Do not dispose expired or unused products! Give it to the collection system determined by Ministry of Environment and Urbanization.

***Marketing authorization holder:***

VEM İLAÇ San. ve Tic. A.Ş  
Söğütözü Mahallesi 2177. Cadde  
No:10B/49 Çankaya/ANKARA/TURKEY

***Manufacturing site:***

VEM İlaç San. ve Tic. A.Ş.  
Çerkezköy Organize Sanayi Bölgesi  
Karaağaç Mahallesi Fatih Bulvarı No: 38  
Kapaklı/TEKİRDAĞ/TURKEY

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