

PATIENT INFORMATION LEAFLET

PALONEX 250 mcg/5 mL solution for injection

Sterile

Administered intravenously.

- **Active substance:** Palonosetron (as hydrochloride)

Each vial of 5 mL of solution contains 250 micrograms palonosetron. (Each ml of solution contains 50 micrograms palonosetron).

- **Excipients:** Mannitol, disodium edetate, sodium citrate, citric acid monohydrate, water for injection, sodium hydroxide solution and hydrochloric acid solution

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 PALONEX is and what it is used for?*
2. *What you need to know before you use PALONEX*
3. *How to use PALONEX?*
4. *What are the possible side effects?*
5. *How to store PALONEX*

Headings are included.

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

- PALONEX is a colorless solution administered intravenously.
- PALONEX is packed in a glass vial containing 5 mL of solution. Each vial contains one dose.
- PALONEX belongs to a group of medicines called serotonin (5HT₃) antagonists.
- This group of drugs works by stopping the effect of serotonin, which can cause nausea and vomiting.
- PALONEX is used in adults, adolescents and children over one month of age to help stop nausea and vomiting when having cancer treatments called chemotherapy.

2. What you need to know before you use PALONEX

DO NOT USE PALONEX if you;

Do not use if you are hypersensitive to palonosetron or other excipients in PALONEX (see list of excipients).

USE PALONEX CAREFULLY:

If;

- You have a blocked bowel or have had repeated constipation in the past
- You are taking PALONEX with other drugs that may cause abnormal heart rhythm, such as amiodarone, nicardipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone,
- You have had heart problems or heart problems run in your family, such as changes in your heart beat ('QT prolongation')
- You have other heart problems,
- You have an imbalance of certain minerals in your blood which has not been treated - such as potassium and magnesium.

If you do not take another cure of chemotherapy, it is not recommended to take PALONEX on the days following the chemotherapy.

If these warnings are applicable to you even for any period of time in the past, please consult your physician.

Use of PALONEX with food and drink

No interaction with food and drink in terms of administration method.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

If you are pregnant or think you may be pregnant, your doctor will not apply PALONEX unless you consider it necessary.

It is not known whether the administration of PALONEX during pregnancy causes any harmful effects.

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 not known whether PALONEX passes into breast milk.

If you are breastfeeding, consult your doctor or pharmacist before using PALONEX.

Driving and using machines

Do not drive or use machines if palonosetron affects you, as it may cause dizziness or fatigue.

Important information about some excipients found in the composition of PALONEX

If you are not hypersensitive to the excipients contained in PALONEX, no adverse effects are expected.

This medicinal product contains less than 1 mmol (23 mg) sodium per vial; in other words, it is essentially “sodium-free”.

Use with other medicines

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. In particular, tell them if you are taking the following medicines:

- Medicines used for depression or anxiety called SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- Medicines used for depression or anxiety SNRIs (serotonin noradrenaline reuptake inhibitors) including venlafaxine, duloxetine

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 PALONEX

Instructions for appropriate use and dose / administration frequency:

PALONEX is normally given by a doctor or nurse about 30 minutes before the start of chemotherapy as intravenous administration.

Use in the elderly:

Route and method of administration:

- It is used by intravenous injection.
- Your doctor or nurse will normally inject PALONEX approximately 30 minutes before the start of chemotherapy.
- 250 micrograms of PALONEX are administered intravenously by rapid injection. The remaining PALONEX from the opened vial is discarded.

Various age groups:

Children and young people (aged 1 month to 17 years):

- The doctor will decide the dose of the drug based on body weight, but the maximum dose is 1500 micrograms.
- PALONEX will be given intravenously by slow infusion.

Elderly use:

It is used according to the dosage recommended by the doctor in the elderly without any dosage adjustment.

Special use cases

Renal / Liver failure:

Patients with impaired renal function do not require a special dose adjustment other than the dose recommended by the doctor. Please consult your doctor as there is no data available for patients with advanced renal disease who are continuing hemodialysis.

Patients with impaired liver function do not require a special dose adjustment other than the dose recommended by the doctor.

Unless your doctor recommends otherwise follow these instructions.

Do not forget to take your medicine on time.

Your doctor will advise you how long your treatment with PALONEX will take. Do not stop treatment early because you cannot get the desired result.

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

If you have used more PALONEX than you should:

If you have used more PALONEX than you should, talk a doctor or pharmacist.

If you forget to use PALONEX:

Your doctor will decide when the missed dose to be administered.

It is important that you follow your physicians' instructions for the next time of the following dose.

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

Effects which may occur when treatment with PALONEX is discontinued:

Not available.

4. What are the possible side effects?

As with all medicines, there may be side effects in people who are sensitive to the ingredients of PALONEX.

If you notice any of the following, stop using PALONEX and inform your doctor IMMEDIATELY, or apply to the emergency service of the nearest hospital:

- Swelling of lips, face, tongue or throat, difficulty breathing or fainting, itching, lumpy rash (hives)

These are all very serious side effects. If you have one of these, you have a serious allergy to PALONEX. You may need urgent medical attention or hospitalization.

All of these are very serious side effects and they are very rare. Side effects are listed as follows.

Very common	: It 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 1000 patients.
Rare	: Less than one in 1000 patients, but more than one in 10,000 patients

Very rare : Less than one in 10000 patients may be seen.
Unknown : It can be seen in too few patients to be determined by the available data.

In Adults:

Common side effects:

- Headache
- Dizziness
- Constipation
- Diarrhea

Uncommon side effects:

- High or low blood pressure
- Abnormal heart beat or decreased blood flow to the heart
- Change in vessel color and / or dilation of vessel
- Potentially high or low levels of potassium in the blood
- High levels of sugar in urine or blood
- Low levels of calcium in the blood
- High levels of bilirubin in the blood
- Some liver enzyme levels are high
- Extreme happiness or anxiety
- Sleepiness or sleep problems
- Decreased appetite or loss of appetite
- Weakness, fatigue, fever or flu-like symptoms
- Skin numbness, burning, tingling or tingling sensation
- Itchy skin rash
- Visual impairment or eye irritation
- Movement sickness (motion sickness)
- Tinnitus
- Hiccups, gas, dry mouth or indigestion
- Abdominal pain
- Difficulty urinating
- Joint pain
- Electrocardiogram abnormalities (QT prolongation)

Very rare side effects:

Allergic reactions to PALONEX (Symptoms may include swelling of lips, face, tongue or throat, difficulty breathing or fainting. You may also experience itching, lumpy rash(hives).

Burning or pain at the injection site.

In Children and Adolescents:

Common:

- Headache

Uncommon:

- Dizziness
- Irregular body movements
- Abnormal heart beat
- Cough or shortness of breath
- Nose bleeding
- Itchy skin rash or hives
- Fever
- Pain on infusion site

Reporting of the side effects:

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.

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

5. How to store PALONEX

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

Store at room temperature below 25°C, protected from light and humidity.

Do not freeze PALONEX. Do not unfreeze if the drug is frozen.

For single use only. The remaining solution from each vial should be discarded.

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

Use in compliance with the expiry date.

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

Do not use PALONEX if you notice any damage in the product and/or its package.

Marketing Authorization Holder:

Haver Trakya İlaç San. ve Tic. A.Ş.
Ulaş OSB Mah. D100 Cad. No:28/1, Ergene 2 OSB
Ergene/TEKİRDAĞ

Manufacturing Sites:

Haver Trakya İlaç San. ve Tic. A.Ş.
Ulaş OSB Mah. D100 Cad. No:28/1, Ergene 2 OSB
Ergene/TEKİRDAĞ
Tel: (0282) 655 55 05

Mefar İlaç Sanayii A.Ş.
Ramazanoğlu Mah. Ensar Cad. No:20
Kurtköy-Pendik / İSTANBUL

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