Package leaflet: Information for the patient

Palonosetron 250 micrograms solution for injection

Palonosetron

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Palonosetron is and what it is used for

Palonosetron belongs to a group of medicines known as serotonin (5HT3) antagonists.

These have the ability to block the action of the chemical, serotonin, which can cause nausea and vomiting.

Palonosetron is used for the prevention of nausea and vomiting associated with cancer chemotherapy in adults, adolescents and children over one month of age.

2. What you need to know before you use Palonosetron

Do not use Palonosetron

- If you are allergic to palonosetron or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Palonosetron

- If you have acute bowel obstruction or a history of repeated constipation.
- If you are using Palonosetron in addition to other medicines that may induce an abnormal heart rhythm such as amiodarone, nicardipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone.
- If you have a personal or family history of alterations in heart rhythm (QT prolongation).
- If you have other heart problems.
- If you have an imbalance of certain minerals in your blood such as potassium and magnesium which has not been treated.

It is not recommended to take Palonosetron in the days following chemotherapy unless you are receiving another chemotherapy cycle.

Other medicines and Palonosetron
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:
SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram;
SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

Pregnancy
If you are pregnant or think you might be, your doctor will not administer Palonosetron to you unless it is clearly necessary.
It is not known whether Palonosetron will cause any harmful effects when used during pregnancy.

Ask your doctor or pharmacist for advice before using any medicine if you are pregnant or think you might be.

Breast-feeding
It is not known if Palonosetron is found in breast milk.
Ask your doctor or pharmacist for advice before using Palonosetron if you are breast-feeding.

Driving and using machines
Palonosetron may cause dizziness or tiredness. If affected, do not drive or use any tools or machines.

Palonosetron contains less than 1 mmol sodium (23 mg) per vial, but if the maximum dose for children (6 vials) is administered the sodium content corresponds to 1.2 mmol sodium (28 mg).

3. How to use Palonosetron

A doctor or nurse will normally inject Palonosetron about 30 minutes before the start of chemotherapy.

Adults
The recommended dose of Palonosetron is 250 micrograms given as a rapid injection into a vein.

Children and Adolescents (aged 1 month to 17 years)
The doctor will decide the dose, depending on bodyweight, however the maximum dose is 1500 micrograms.
Palonosetron will be given as a slow infusion into a vein.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:
very common (may affect more than 1 in 10 people); common (may affect up to 1 in 10 people); uncommon (may affect up to 1 in 100 people); rare (may affect up to 1 in 1,000 people); very rare (may affect up to 1 in 10,000 people); not known (frequency cannot be estimated from the available data).

Common side effects
- headache

- dizziness
- constipation
- diarrhoea

Uncommon side effects
- high or low blood pressure
- abnormal heart rate or lack of blood flow to the heart
- change in the colour of the vein and/or veins becoming larger
- abnormally high or low levels of potassium in the blood
- high levels of sugar in the blood or sugar in the urine
- low levels of calcium in the blood
- high levels of the pigment bilirubin in the blood
- high levels of certain liver enzymes
- elevated moods or feelings of anxiousness
- sleepiness or trouble sleeping
- decrease or loss of appetite
- weakness, tiredness, fever or flu like symptoms
- numbness, burning, prickling or tingling sensations on the skin
- itchy skin rash
- impaired vision or eye irritation
- motion sickness
- ringing in the ear
- hiccups, flatulence, dry mouth or indigestion
- abdominal (stomach) pain
- difficulty urinating
- joint pain
- electrocardiogram abnormalities (QT prolongation)

Very rare side effects
Allergic reactions to Palonosetron.
The signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing, you could also notice an itchy, lumpy rash (hives), burning or pain at the site of injection.

Children and Adolescents:
Common
• headache

Uncommon
• dizziness
• jerky body movements
• abnormal heart rate
• coughing or shortness of breath
• nosebleed
• itchy skin rash or hives
• fever
• pain at the site of infusion

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Palonosetron

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use Palonosetron if you notice discolouration, cloudiness or particles, it should be a clear, colourless solution.

Single use only, any unused solution should be disposed of.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Palonosetron contains

- The active substance is palonosetron (as hydrochloride).
  Each ml of solution contains 50 micrograms palonosetron. Each vial of 5 ml of solution contains 250 micrograms of palonosetron.

- The other ingredients are mannitol (E421), disodium edetate, sodium citrate (E331), citric acid monohydrate (E330), and water for injections, sodium hydroxide and hydrochloric acid (E507).

What Palonosetron looks like and contents of the pack

Palonosetron solution for injection is a clear, colourless solution, free from visible particles with a pH of 4.5 – 5.5 and is supplied in a pack of one Type I glass vial with grey rubber stopper and aluminium cap, which contains 5 ml of the solution. Each vial contains one dose.

Available in packs of 1 vial containing 5 ml of solution.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is
Flynn Pharma Ltd
Marine House
Clanwilliam Place
Dublin 2
Ireland

The manufacturer is
Haupt Pharma Wolfratshausen GmbH
Pfaffenrieder Straße 5
82515 Wolfratshausen
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