

Package leaflet: Information for the user

Palonosetron 250 micrograms solution for injection

Palonosetron

Read all of this leaflet carefully before you are given 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 nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Palonosetron solution for injection is and what it is used for
2. What you need to know before you are given Palonosetron solution for injection
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1. What Palonosetron solution for injection is and what it is used for

Palonosetron solution for injection contains the active substance palonosetron. This belongs to a group of medicines called 'serotonin (5HT₃) antagonists'.

Palonosetron solution for injection is used in adults, adolescents and children over one month of age to help stop you feeling or being sick (nausea and vomiting) when having cancer treatments called chemotherapy.

It works by blocking the action of a chemical called serotonin, which can cause you to feel sick or to vomit.

2. What you need to know before you are given Palonosetron solution for injection

Do not take Palonosetron solution for injection if:

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

You will not be given Palonosetron solution for injection if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before you are given Palonosetron solution for injection if:

- you have a blocked bowel or have had repeated constipation in the past
- you have had heart problems or heart problems run in your family, such as changes in your heart beat ('QT prolongation')
- you have an imbalance of certain minerals in your blood which has not been treated - such as potassium and magnesium.

If any of the above applies to you (or you are not sure), talk to your doctor or nurse before you are given Palonosetron solution for injection.

. Other medicines and Palonosetron solution for injection

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 for depression or anxiety

Tell your doctor or nurse if you are taking any medicines for depression or anxiety, including:

- medicines called SSRIs ('selective serotonin reuptake inhibitors') – such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- medicines called SNRIs ('serotonin noradrenaline reuptake inhibitors') – such as venlafaxine, duloxetine (can lead to the development of serotonin syndrome and should be used with caution).

Medicines that can affect your heart beat

Tell your doctor or nurse if you are taking any medicines that affect your heart beat – this is because they could cause a heart beat problem when taken with Palonosetron solution for injection. This includes:

- medicines for heart problems such as amiodarone, nicardipine, quinidine
- medicines for infections such as moxifloxacin, erythromycin
- medicines for serious mental health problems such as haloperidol, chlorpromazine, quetiapine, thioridazine
- a medicine for feeling or being sick (nausea and vomiting) called domperidone.

If any of the above applies to you (or you are not sure), talk to your doctor or nurse before taking Palonosetron solution for injection – this is because these medicines could cause a heart beat problem when taken with Palonosetron solution for injection.

Pregnancy

If you are pregnant or think you might be pregnant, your doctor will not give you Palonosetron solution for injection unless it is clearly necessary. This is because we do not know if Palonosetron solution for injection may harm the baby.

Ask your doctor or nurse for advice before being given this medicine if you are pregnant or think you might be.

Breast-feeding

It is not known if Palonosetron solution for injection is found in breast milk.

Ask your doctor or nurse for advice before being given this medicine if you are breast-feeding.

Driving and using machines

You may feel dizzy or tired after being given this medicine. If this happens, do not drive or use any tools or machines.

Palonosetron solution for injection contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How you are given Palonosetron solution for injection

Palonosetron solution for injection is normally given by a doctor or nurse.

- You will be given the medicine about 30 minutes before the start of chemotherapy.

Adults

- The recommended dose of Palonosetron solution for injection is 250 micrograms.
- It is given as an injection into a vein over 30 seconds.

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

- The doctor will work out the right dose based on bodyweight.
- The recommended dose is 20 micrograms per kilogram of bodyweight
- The maximum dose is 1500 micrograms.

- Palonosetron solution for injection will be given as a drip (a slow infusion into a vein) over 15 minutes.

It is not recommended you are given Palonosetron solution for injection in the days following chemotherapy unless you are going to have another chemotherapy cycle.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects:

- allergic reaction - the signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing, an itchy, lumpy rash (hives). This is very rare: may affect up to 1 in 10,000 people.

Tell your doctor straight away if you notice any of the serious side effects listed above.

Other side effects

Tell your doctor if you notice any of the following side effects:

Adults

Common: may affect up to 1 in 10 people

- headache, feeling dizzy,
- constipation, diarrhoea.

Uncommon: may affect up to 1 in 100 people

- change in the colour of the vein and veins becoming larger
- feeling happier than usual or feeling anxious
- feeling sleepy or trouble sleeping
- decrease or loss of appetite
- weakness, feeling tired, 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, passing wind (flatulence), dry mouth or indigestion
- abdominal (stomach) pain
- difficulty passing water (urinating)
- joint pain.

Tell your doctor if you notice any of the side effects listed above.

Uncommon side effects shown in tests: may affect up to 1 in 100 people

- high or low blood pressure
- abnormal heart rate or lack of blood flow to the heart
- 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
- ECG (electrocardiogram) abnormalities ('QT prolongation').

Very rare: may affect up to 1 in 10,000 people

- Burning, pain or redness at the injection site

Children and young people

Common: may affect up to 1 in 10 people

- headache.

Uncommon: may affect up to 1 in 100 people

- 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.

Tell your doctor if you notice any of the side effects listed above.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Palonosetron solution for injection

- Keep this medicine out of the sight and reach of children.
- Keep the vial in the outer carton in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the vial and carton after 'EXP'.
- This medicine does not require any special temperature storage conditions.
- Single use only, any unused solution should be disposed of.

6. Contents of the pack and other information

What Palonosetron solution for injection contains

- The active substance is palonosetron (as hydrochloride). Each ml of solution contains 50 micrograms palonosetron (as hydrochloride). Each vial of 5 ml of solution contains 250 micrograms of palonosetron (as hydrochloride).
- The other ingredients are mannitol, disodium edetate, sodium citrate, citric acid monohydrate, water for injections, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment).

What Palonosetron solution for injection looks like and contents of the pack

Palonosetron solution for injection is a clear, colourless solution and is supplied in a pack of one Type I clear glass vial with chlorobutyl siliconised grey rubber stopper and aluminium flip-off cap with red polypropylene disk, 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

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