



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 is and what it is used for
2. What you need to know before you are given Palonosetron
3. How you are given Palonosetron
4. Possible side effects
5. How to store Palonosetron
6. Contents of the pack and other information

1. What Palonosetron is and what it is used for

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

Palonosetron 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

You should not be given Palonosetron:

- if you are allergic to palonosetron or any of the other ingredients of this medicine (listed in section 6).
- You will not be given this medicine 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 this medicine:
- if you have a blocked bowel or have had repeated constipation in the past;
 - if you have had heart problems or heart problems run in your family, such as changes in your heart beat ('QT prolongation');
 - if 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 this medicine.

Other medicines and Palonosetron

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. 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 this medicine - this is because these medicines could cause a heartbeat problem when taken with Palonosetron.

Pregnancy

If you are pregnant or think you might be pregnant, your doctor will not give you this medicine unless it is clearly necessary. This is because it is not known if palonosetron 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 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 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

Palonosetron 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 is 250 micrograms.
- It is given as an injection into a vein.

Children and adolescents (aged 1 month to 17 years)

- The doctor will work out the right dose based on bodyweight.
- The maximum dose is 1500 micrograms.
- Palonosetron will be given as a drip (a slow infusion into a vein).

It is not recommended you are given this medicine 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.

Pharmacode



Pharmacode

Pharmacode

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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:

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

- allergic reaction-the signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing, an itchy, lumpy rash (hives)

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

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 Website: 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

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

This medicine does not require any special storage conditions.

Shelf life after opening the vial
Use immediately after opening the vial.

Shelf life after dilution
Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C and 2 to 8 °C.

From a microbiological point of view, the diluted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

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.

For single use only. Any unused solution should be discarded.

The solution should be inspected visually prior to use. Only clear and colourless solutions free from visible particles should be used.

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 (as hydrochloride). Each vial of 5 ml of solution contains 250 micrograms palonosetron (as hydrochloride).

– The other ingredients are mamilol, disodium edetate, sodium citrate, citric acid monohydrate, hydrochloric acid concentrated (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

What Palonosetron looks like and contents of the pack

Clear, colourless solution, free from visible particles.

5 ml of solution is filled in Type I clear borosilicate tubular glass vials with crimp neck. The vials are closed with bromobutyl rubber stoppers and sealed with aluminium flip-off seals. Vials are packed into outer cartons.

Pack size: 1 vial of 5 ml.

Marketing authorisation holder

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Place for AS Kalceks internal code

Place for bleedmarks