

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Palonosetron Accord 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 pharmacist or nurse.
- If you get any side effects, talk to your doctor or 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 Accord is and what it is used for
2. What you need to know before you are given Palonosetron Accord
3. How Palonosetron Accord is given
4. Possible side effects
5. How to store Palonosetron Accord
6. Contents of the pack and other information

1. What Palonosetron Accord is and what it is used for

Palonosetron Accord 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 Accord 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 are given Palonosetron Accord

Do not use Palonosetron Accord:

- 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, pharmacist or nurse before using Palonosetron Accord.

- if you have acute bowel obstruction or a history of repeated constipation.
- if you are using palonosetron accord 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 accord in the days following chemotherapy unless you are receiving another chemotherapy cycle.

Other medicines and Palonosetron Accord

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

Selective serotonin reuptake inhibitors (SSRIs) 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 and breast-feeding

Pregnancy

If you are pregnant or think you might be, your doctor will not administer palonosetron accord to you unless it is clearly necessary.

It is not known whether palonosetron accord 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 accord is found in breast milk.

Ask your doctor or pharmacist for advice before using palonosetron accord if you are breast-feeding.

Driving and using machines

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

Palonosetron Accord contains sodium

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

3. How Palonosetron Accord is given

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

Adults

The recommended dose of palonosetron accord 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 1,500 micrograms. Palonosetron accord 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, pharmacist or nurse.

4. Possible side effects

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

Adults

Common: may affect up to 1 in 10 people

- headache
- dizziness
- constipation and diarrhoea.

Uncommon: may affect up to 1 in 100 people

- high or low blood pressure
- abnormal heart rate or lack of blood flow to the heart
- change in the color 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 feeling 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: may affect up to 1 in 10,000 people

- allergic reactions to palonosetron accord

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: may affect up to 1 in 10 people

- headache

Uncommon:

may affect up to 1 in 100 people

- dizziness
- jerky body movement
- abnormal heart rate
- cough and shortness of breath
- nose bleed
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard](http://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 Accord

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 carton and the vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.
Single use only, dispose of any unused solution.

6. Contents of the pack and other information

What Palonosetron Accord contains

- The active substance is palonosetron (as hydrochloride).
Each ml of solution contains 50 micrograms of palonosetron. Each vial of 5ml of solution contains 250 micrograms of palonosetron.
- The other ingredients are mannitol, disodium edetate, sodium citrate, citric acid monohydrate, sodium hydroxide (for pH adjustment), hydrochloric acid, concentrated (for pH adjustment) and water for injections. (See section 2 Palonosetron Accord contains sodium).

What Palonosetron Accord looks like and contents of the pack

Palonosetron Accord solution for injection is a clear, colourless solution supplied in a 6 ml glass vial, closed with chlorobutyl rubber stopper and sealed with a flip-off aluminium seal. Each vial contains one dose.

Pack size: one vial

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This leaflet was last revised in 04/2021