

Product Name: Palonosetron Fresenius Kabi 250microgram		Territory: GB	Colour: ● BLACK	1. Draft	01.06. 2016 13:15 Uhr		Variable Data:	
Type of Packaging: PIL	Dosage: 5ml VIAL			1. Correction	02.06. 2016 08:03 Uhr			
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Pharma-Code (Laetus) x	EAN Code:							
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Package leaflet: Information for the user

Palonosetron
250 micrograms solution
for injection

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, pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Palonosetron 250 micrograms solution for injection; in the rest of the leaflet it will be called “Palonosetron”.

What is in this leaflet

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

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, pharmacist or nurse 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 use 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 and breast-feeding

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.

It is not known if Palonosetron is found in breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

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

Palonosetron contains sodium

This medicinal product contains 0.04 mmol (or 0.91 mg) sodium per ml. Maximum dose for children contains 1.19 mmol (or 27.3 mg) sodium. To be taken into consideration for patients on a controlled sodium diet.

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 Fresenius Kabi 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.

Possible side effects and their frequencies are listed below:

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

- 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 (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

The following information is intended for healthcare professionals only:

Posology and method of administration

Adults

250 micrograms palonosetron administered as a single intravenous bolus approximately 30 minutes before start of chemotherapy. Palonosetron should be injected over 30 seconds.

Elderly people

No dose adjustment is necessary for the elderly.

Children and Adolescents (aged 1 month to 17 years):

20 micrograms/kg (the maximum total dose should not exceed 1500 micrograms) palonosetron administered as a single 15 minute intravenous infusion beginning approximately 30 minutes before the start of chemotherapy.

Incompatibilities

This medicinal product must not be mixed with other medicinal products.

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- 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 the national reporting system **For UK** - via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For Ireland - 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 label. The expiry date refers to the last day of that month. Do not use this medicine if the solution is not clear or has visible particles. This medicine does not require any special storage conditions. 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 dihydrate, sodium citrate dihydrate (E331), citric acid anhydrous (E330) and water for injections, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment).

What Palonosetron looks like and contents of the pack

Palonosetron solution for injection is a clear, colorless solution and is supplied in single use glass vials closed with halobutyl rubber stopper and sealed with aluminium - plastic tear-off cap. Pack sizes: 1 or 10 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fresenius Kabi Ltd.
Cestrian Court
Eastgate Way, Manor Park
Runcorn, Cheshire
WA7 1NT
United Kingdom

Manufacturer

Fresenius Kabi Austria GmbH
Hafnerstrasse 36
8055 Graz
Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Belgium	Palonosetron Fresenius Kabi 250 microgram oplossing voor injectie, solution injectable, Injektionslösung
Czech Republic	Palonosetron Fresenius Kabi 250 mikrogramů injekční roztok
Denmark	Palonosetron Fresenius Kabi

Finland	Palonosetron Fresenius Kabi 250 mikrog injektioneste, liuos
France	PALONOSETRON FRESENIUS KABI 250 microgrammes/ 5 ml, solution injectable
Germany	Palonosetron Fresenius Kabi 250 Mikrogramm Injektionslösung
Ireland	Palonosetron 250 micrograms solution for injection
Italy	Palonosetron Fresenius Kabi
Luxembourg	Palonosetron Fresenius Kabi 250 Mikrogramm Injektionslösung
Malta	Palonosetron 250 micrograms solution for injection
Norway	Palonosetron Fresenius Kabi
Poland	Palonosetron Fresenius Kabi
Portugal	Palonossetrom Fresenius Kabi
Romania	Palonosetron Fresenius Kabi 250 micrograme soluție injectabilă
Slovak Republic	Palonosetron Fresenius Kabi 250 mikrogramov injekčný roztok
Slovenia	Palonosetron Fresenius Kabi 250 mikrogramov raztopina za injiciranje
Spain	Palonosetron Fresenius Kabi 250 microgramos Solución inyectable
Sweden	Palonosetron Fresenius Kabi 250 mikrog injektionsvätska, lösning
The Netherlands	Palonosetron Fresenius Kabi 250 microgram, oplossing voor injectie
United Kingdom	Palonosetron 250 micrograms solution for injection

This leaflet was last revised in April 2016.



Special precautions for storage

This medicinal product does not require any special storage conditions.

Special precautions for disposal

Single use only, any unused solution should be discarded.

Any unused product or waste material should be disposed of in accordance with local requirements.