

**Package leaflet: Information for the user**

**Palonosetron 250 micrograms solution for injection in pre-filled syringe**

**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 pre-filled syringe; 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 Palonosetron
3. How to use 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 belongs to a group of medicines known as serotonin (5HT<sub>3</sub>) 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 adult patients.

**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.

**Children and adolescents**

Palonosetron Fresenius Kabi in pre-filled syringes is not recommended for use in children and adolescents. For this population Palonosetron Fresenius Kabi in glass vials can be used.

**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 medicine contains less than 1 mmol sodium (23 mg) per pre-filled syringe, that is essentially 'sodium-free'.

**3. How to use Palonosetron**

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

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

For children and adolescents Palonosetron in vials should be used.

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:

**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.

**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](http://www.mhra.gov.uk/yellowcard)

**For Ireland** - HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**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 population*

No dose adjustment is necessary for the elderly.

**Incompatibilities**

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

**Special precautions for storage**

This medicinal product does not require any special storage conditions.

**Special precautions for disposal and other handling**

Single use only, any unused solution should be discarded.

## 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 pre-filled syringe 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 in pre-filled syringe is a clear, colorless solution and is supplied in single use pre-filled plastic syringes composed of a barrel of cyclo olefin copolymer material and a plunger and tip cap of halobutyl rubber.

Pack sizes:

1 or 10 pre-filled syringes

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

For UK:

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

For IRL:

Fresenius Kabi Deutschland GmbH  
Else-Kroener Strasse 1,  
Bad Homburg v.d.H. 61352,  
Germany

### 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<br>Fresenius Kabi 250<br>microgram oplossing<br>voor injectie in een<br>voorgevulde spuit,<br>solution injectable<br>en seringue<br>pré-remplie,<br>Injektionslösung in<br>einer Fertigspritze |
| Denmark                  | Palonosetron<br>Fresenius Kabi  |
| Finland                  | Palonosetron<br>Fresenius Kabi 250<br>mikrog injektioneste,<br>liuos, esitäytetty<br>ruisku   |
| France                   | PALONOSETRON<br>FRESENIUS KABI<br>250 microgrammes/<br>5 ml, solution<br>injectable en<br>seringue pré-remplie  |

|                 |  |
|-----------------|--|
| Ireland         | Palonosetron<br>250 micrograms<br>solution for injection<br>in pre-filled syringe                          |
| Italy           | Palonosetron<br>Fresenius Kabi   |
| Malta           | Palonosetron<br>250 micrograms<br>solution for injection<br>in pre-filled syringe                          |
| Norway          | Palonosetron<br>Fresenius Kabi   |
| Poland          | Palonosetron<br>Fresenius Kabi   |
| Portugal        | Palonosetrom<br>Fresenius Kabi   |
| Romania         | Palonosetron<br>Fresenius Kabi 250<br>micrograme soluție<br>injectabilă în seringă<br>preumplută           |
| Spain           | Palonosetron<br>Fresenius Kabi 250<br>microgramos<br>solución inyectable<br>en jeringa<br>precargada       |
| Sweden          | Palonosetron<br>Fresenius Kabi 250<br>mikrog<br>injektionsvätska,<br>lösning i förfylld<br>spruta          |
| The Netherlands | Palonosetron<br>Fresenius Kabi 250<br>microgram,<br>oplossing voor<br>injectie in een<br>voorgevulde spuit |
| United Kingdom  | Palonosetron<br>250 micrograms<br>solution for injection<br>in pre-filled syringe                          |

**This leaflet was last revised in May 2019.**



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

### Application of pre-filled syringes:

Sterility has to be ensured. The outer surface of the syringe and the plunger rod are not sterile!

- 1) Take out the syringe from the packaging
- 2) Remove the tip cap from the syringe and connect the infusion line, needle or cannula to the syringe. Get rid of the air bubble (a small bubble can remain) and the ready-to-use syringe will be administered manually.