Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986
This medicine is sold with a doctor's prescription only

Paloxi® Capsules

Active ingredient:
Each capsule contains 0.5 mg (=500 micrograms) of palonosetron as hydrochloride salt.
For the list of the other ingredients, please see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist.
This medicine has been prescribed for treating your condition. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

1. What is the medicine intended for?
The medicine is intended for prevention of nausea and vomiting in adults as a result of chemotherapy treatment for cancer.

Therapeutic group:
Anti-nausea and vomiting agent (antiemetic): serotonin receptor blocker (5-HT3).

2. Before using the medicine
Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for the list of the other ingredients, please see section 6).

Special warnings regarding the use of this medicine:

Before treatment with the medicine tell your doctor if:
- You suffer from a blocked bowel or if you suffer or have suffered in the past from recurring constipation.
- You or someone in your family suffers or has suffered in the past from heart problems, such as changes in heartbeat (QT interval prolongation).
- You suffer from an imbalance of certain minerals in your blood (which is not treated) - such as potassium and magnesium.

Children and adolescents:
Do not give this medicine to children.

Drug interactions: If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. In particular if you are taking:

Medicines for treating depression or anxiety:
Medicines from the SSRIs group (such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram) or from the SNRIs group (such as venlafaxine, duloxetine). The combination with Paloxi may cause serotonin syndrome.

Medicines that affect the heartbeat - the combination of these medicines with Paloxi may cause heartbeat problems. These medicines include amongst others:

- Medicines for treating heart problems, such as amiodarone, nicardipine, quinidine;
- Medicines for treating infections, such as moxifloxacin, erythromycin;
- Medicines for treating certain mental health problems, such as haloperidol, chlorpromazine, quetiapine, thioridazine;
- An anti-nausea and vomiting medicine called domperidone.

Use of this medicine and food

The medicine can be taken regardless of mealtimes.

Pregnancy and breastfeeding:

Consult your doctor before taking this medicine if you are pregnant, think you are pregnant or are breast-feeding.

- If you are pregnant or think you are pregnant, the doctor will prescribe Paloxi for you only if it is clearly necessary, since there is no information on the effect of the medicine on the baby.
- It is not known whether the medicine is secreted into breast milk, so do not breast-feed during the treatment with the medicine.

Driving and use of machinery:

Use of this medicine may cause dizziness, sleepiness and/or tiredness. If you experience these symptoms, do not drive or operate machinery.

Important information about some of the medicine's ingredients

- Every capsule contains 7 mg sorbitol (a type of sugar). If you have an intolerance to some sugars, inform your doctor before taking the medicine.
- The capsules may contain traces of lecithin derived from soya. If you are allergic to peanuts or soya, do not take this medicine. Refer to your doctor immediately if you notice any sign of an allergic reaction. The symptoms of an allergic reaction may include: urticaria (hives), skin rash, itching, difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat; a drop in blood pressure.

3. How to use this medicine?

Always use according to your doctor's instructions. You should check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment with the medicine.

The dosage and the manner of treatment will be determined by the doctor only.

The standard dosage is usually: one capsule, about an hour before the start of the chemotherapy treatment.

The medicine can be taken regardless of mealtimes.

Do not exceed the recommended dose.

It is not recommended to take Paloxi in the days following the chemotherapy treatment, unless you are going to have another treatment cycle.

Swallow the capsule whole. Do not chew or open the capsule.

If you have accidentally taken a higher dosage

If you think that you may have taken a higher dose than recommended, tell your doctor immediately.

If you forgot to take the medicine

If you think you have forgotten to take the dose, tell your doctor.

If you stop taking the medicine
Do not stop taking the medicine without consulting your doctor. If you decide not to use this medicine (or another similar medicine), the chemotherapy treatment may cause you nausea and vomiting.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

Like any medicine, the use of Paloxi may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Contact your doctor immediately, if the following serious side effect appears:
Allergic reaction. The symptoms may include: swelling of the lips, face, tongue or throat, breathing difficulties or collapsing, rash (hives). This reaction is very rare (may affect up to 1 in 10,000 people).

Additional side effects:

Common side effects (appear in 1-10 users out of 100):

- Headache.

Uncommon side effects (appear in 1-10 users out of 1,000):

- Sleeping problems, shortness of breath, eye swelling, disturbance of the heart electrical impulses, constipation, feeling sick (nausea), high level of bilirubin in the blood (a marker of liver problems), muscle pain.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Dizziness, sleepiness, tiredness

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

In addition to the active ingredient, the capsules also contain:
Glycerol monocaprylocaprate, gelatin, sorbitol blend (sorbitol, sorbitan, glycerin), glycerin, purified water, polyglyceryl oleate, titanium dioxide, butylated hydroxyanisole.

The capsules contain sorbitol and may also contain traces of soya. See also section 2, 'Important information about some of the medicine's ingredients'.

What does the medicine look like and what does the package contain?
Light beige soft capsule containing a clear yellow liquid. The package contains one or five capsules in a blister pack. Not all pack sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Manufacturer: Helsinn Birex Pharmaceuticals Ltd., Dublin, Ireland.

Medicine registration number in the National Medicines Registry of the Ministry of Health:
162-48-35784

This leaflet was checked and approved by the Ministry of Health in July 2019.

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