**Teva Pharmaceuticals (Pty) Ltd.**
**Palonosetron 0,25 Teva**
**Each ml of solution contains 0,05 mg palonosetron (as hydrochloride).**

**PATIENT INFORMATION LEAFLET:**

**SCHEDULING STATUS:** **S4**

**PALONOSETRON 0,25 TEVA (solution for injection)**

**Palonosetron (as hydrochloride)**

Each 5 ml vial contains less than 1 mmol sodium (23 mg)

**Read all of this leaflet carefully before you start using PALONOSETRON 0,25 TEVA:**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

**WHAT IS IN THIS LEAFLET:**

**1. WHAT PALONOSETRON 0,25 TEVA IS AND WHAT IT IS USED FOR**

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE PALONOSETRON 0,25 TEVA**

**3. HOW TO USE PALONOSETRON 0,25 TEVA**

**4. POSSIBLE SIDE EFFECTS**

**5. HOW TO STORE PALONOSETRON 0,25 TEVA**

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

## 1. WHAT PALONOSETRON 0,25 TEVA IS AND WHAT IT IS USED FOR:

PALONOSETRON 0,25 TEVA belongs to a group of medicines known as serotonin ($5\text{-}HT_3$) antagonists.

These have the ability to block the action of the chemical, serotonin, which can cause nausea and vomiting.

PALONOSETRON 0,25 TEVA is indicated for the prevention of acute nausea and vomiting associated with moderately or highly emetogenic cancer chemotherapy.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE PALONOSETRON 0,25 TEVA:

***Do not use PALONOSETRON 0,25 TEVA:***

If you are allergic to palonosetron or any of the other ingredients of PALONOSETRON 0,25 TEVA (listed in **section 6).**

***Warnings and precautions:***

Talk to your doctor, pharmacist or nurse before using PALONOSETRON 0,25 TEVA**:**

- if you have acute bowel obstruction or a history of repeated constipation
- if you are using PALONOSETRON 0,25 TEVA 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 0,25 TEVA in the days following chemotherapy unless you are receiving another chemotherapy cycle.

***Other medicines and PALONOSETRON 0,25 TEVA:***

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (this includes all complementary or traditional medicines). Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with PALONOSETRON 0,25 TEVA:

- 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, breastfeeding and fertility:***

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

*Pregnancy:*

It is not known whether PALONOSETRON 0,25 TEVA will cause any harmful effects when used during pregnancy. You should therefore not use PALONOSETRON 0,25 TEVA during pregnancy.

*Breastfeeding:*

It is not known if PALONOSETRON 0,25 TEVA is found in breast milk. You should stop breastfeeding your baby whilst on therapy with PALONOSETRON 0,25 TEVA.

***Driving and using machines:***

PALONOSETRON 0,25 TEVA may cause dizziness or tiredness. If affected, do not drive or use any tools or machines. It is not always possible to predict to what extent PALONOSETRON 0,25 TEVA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PALONOSETRON 0,25 TEVA affects them.

***PALONOSETRON 0,25 TEVA contains sodium:***

Each vial contains less than 1 mmol sodium (23 mg) per vial, that is to say it is essentially sodium-free.

**3. HOW TO USE PALONOSETRON 0,25 TEVA:**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself PALONOSTERON 0,25 TEVA. It will be given to you by a person who is qualified to do so.

A doctor or nurse will normally inject PALONOSETRON 0,25 TEVA about 30 minutes before the start of chemotherapy.

***Adults:***

0,25 mg PALONOSETRON 0,25 TEVA is administered as a single intravenous injection approximately 30 minutes before the start of chemotherapy.

PALONOSETRON 0,25 TEVA should be injected over 30 seconds.

Repeated dosing of PALONOSETRON 0,25 TEVA within a seven day interval is not recommended.

***Use in children and adolescents:***

You will not be given PALONOSETRON 0,25 TEVA if you are under 18 years of age.

**4. POSSIBLE SIDE EFFECTS:**

PALONOSETRON 0,25 TEVA can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALONOSETRON 0,25 TEVA, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, tell your doctor immediately:

- allergic reactions to PALONOSETRON 0,25 TEVA. 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to PALONOSETRON 0,25 TEVA. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- dizziness
- high or low blood pressure
- abnormal heart rate or lack of blood flow to the heart
- weakness, tiredness, fever or flu like symptoms
- abdominal (stomach) pain
- difficulty urinating.

Tell your doctor if you notice any of the following:

The side effects listed below may also occur after receiving PALONOSETRON 0,25 TEVA:

*Frequent:*

- headache

- constipation
- diarrhoea.

*Less frequent:*

- 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
- 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
- joint pain
- electrocardiogram abnormalities (QT prolongation).

*Frequency unknown:*

- Myocardial ischemia (sudden chest pain and chest tightness).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

***Reporting of side effects:***

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Reaction Reporting Form**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PALONOSETRON 0,25 TEVA.

**5. HOW TO STORE PALONOSETRON 0,25 TEVA:**

Store between 20 °C and 25 °C.

Protect from freezing.

Protect from light.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the vial and carton. The expiry date refers to the last day of that month.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION:**

***What PALONOSETRON 0,25 TEVA contains:***

The active substance is palonosetron (as hydrochloride).

Each ml of solution contains 0,05 mg palonosetron.

Each 10 ml glass vial of 5 ml of solution contains 0,25 mg palonosetron.

Each vial contains less than 1 mmol sodium (23 mg).

The other ingredients are: mannitol, edetate disodium, sodium citrate dehydrate, citric Acid monohydrate, hydrochloric acid solution 10 % w/w, sodium hydroxide solution 10 % w/w and water for injection.

**What PALONOSETRON 0,25 TEVA looks like and contents of the pack:**

PALONOSETRON 0,25 TEVA is a sterile clear colourless solution and is supplied in a pack of one 10 ml single use Type I glass vial with a grey chlorobutyl rubber stopper and blue aluminium cap, which contains 5 ml of the solution individually packaged in a carton.

Each vial contains one dose.

Available in packs of one 10 ml vial containing 5 ml of solution.

**Holder of certificate of registration:**

Teva Pharmaceuticals (Pty) Ltd.

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**Palonosetron 0,25 Teva**
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