PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PALTON 250 micrograms solution for injection

Palonosetron

Read all of this leaflet carefully before you are given PALTON.

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

What is in this leaflet

1. What PALTON is and what it is used for

2. What you need to know before you are given PALTON

3. How to use PALTON

4. Possible side effects

5. How to store PALTON

6. Contents of the pack and other information

1. What PALTON is and what it is used for

PALTON contains the active ingredient palonosetron which belongs to a group of medicines known as serotonin ($5HT_3$) antagonists. These have the ability to block the action of the chemical, serotonin, which can cause nausea and vomiting.

PALTON is used for the prevention of nausea and vomiting associated with cancer chemotherapy. PALTON can be used in patients 18 years and older.

2. What you need to know before you are given PALTON

PALTON should not be given to you:

- if you are hypersensitive (allergic) to palonosetron or any of the other ingredients of PALTON (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have acute bowel obstruction or a history of constipation.
- if you are taking PALTON in addition to other medicines that may induce an abnormal heart rhythm or if you are taking anti-dysrhythmic medicines (medicines to control your heartbeat).
- if you have a personal or family history of changes in heart rhythm (QT prolongation).
- if you have heart problems including a problem called “congenital QT syndrome”.
- if you have low potassium or magnesium levels in your blood.
- if you are taking PALTON in addition to other medicines to treat depression or anxiety.

It is not recommended that you are given PALTON in the days following chemotherapy unless you are receiving another chemotherapy cycle.

Other medicines and PALTON

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)

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

- “water pills” (diuretics);
- medicines to control your heartbeat (anti-dysrhythmic medicines);
- medicines used to treat depression and/or anxiety.

Pregnancy and breastfeeding

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 you are given PALTON.

Pregnancy

It is unknown whether PALTON will cause any harmful effects when used during pregnancy. You should therefore not use PALTON during pregnancy.

Breastfeeding

It is unknown if PALTON is found in breast milk. You should stop breastfeeding your baby whilst on therapy with PALTON.

Driving and using machines

It is not always possible to predict to what extent PALTON may interfere with your daily activities. Do not engage in any activities until you are aware of the measure to which PALTON affects you.

PALTON may cause dizziness or tiredness. If this happens to you, do not drive, use any tools or machines.

PALTON contains sodium

PALTON contains less than 1 mmol sodium (23 mg) per vial, i.e., essentially ‘sodium- free’.

3. How to use PALTON

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

You will not be expected to give yourself PALTON. It will be given to you by a person who is qualified to do so.

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

The recommended dose of PALTON is 250 micrograms (1 vial) given as a rapid injection into a vein.

Repeat dosing of PALTON within a seven-day interval after your initial dose is not recommended.

Your doctor will tell you how long your treatment with PALTON will last. Do not stop treatment earlier than your doctor has told you to. If you have the impression that the effect of PALTON is too strong or too weak, tell your doctor or pharmacist.

If you receive more PALTON than you should

Since a health care provider will administer PALTON, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PALTON

Since a health care provider will administer PALTON, it is unlikely that the dose will be missed.

4. Possible side effects

PALTON can have side effects.

Not all side effects reported for PALTON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALTON, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.
- fainting.

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

Tell your doctor immediately if you notice any of the following:

- abnormal heart rate or rhythm (heart beating too fast and too slow) or lack of blood flow to the heart, which could cause chest pain or difficulty breathing.
- abnormalities seen in your ECG (electrocardiogram) including those known as 'QT prolongation'.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects:

- headache and dizziness.
- constipation and diarrhoea.

Less frequent side effects:

- high or low blood pressure; change in the color of the vein and/or veins becoming larger.
- abnormally high or low levels of potassium in the blood or low levels of calcium in the blood.
- high levels of sugar in the blood or sugar in the urine.
- high levels of the pigment bilirubin in the blood or high levels of certain liver enzymes.
- decrease or loss of appetite, elevated moods, feeling of anxiousness, sleepiness, or trouble sleeping.

- weakness, tiredness, fever or flu like symptoms.
- numbness, burning, prickling or tingling sensations on the skin; itchy or allergic skin rash.
- impaired vision, eye irritation, motion sickness or ringing in the ear.
- hiccups, flatulence, dry mouth, indigestion or abdominal (stomach) pain.
- difficulty urinating.
- joint pain.
- allergic reactions. The signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing, and you could also notice an itchy, lumpy rash (hives).
- burning, discomfort, pain or hardening of the skin at the site of injection.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug 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 PALTON.

5. How to store PALTON

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C.
- Protect from light.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PALTON contains

The active substance is palonosetron (as hydrochloride).

The other ingredients are citric acid monohydrate, disodium edetate, hydrochloric acid concentrated (for pH adjustment), mannitol, sodium citrate, sodium hydroxide (for pH adjustment), and water for injection.

What PALTON looks like and contents of the pack

PALTON is a solution for injection that is clear and colourless.

PALTON is supplied in clear, transparent 5 ml glass vials, closed with chlorobutyl rubber stoppers and sealed with aluminium seals with red flip-off buttons. The vials are packed in outer cartons.

Each vial contains one dose.

Holder of Certificate of Registration

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