

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****CHEMSENTRON 50 µg/ml solution for injection****Palonosetron****Sugar free****Please read this leaflet carefully before you are given CHEMSENTRON**

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

What is in this leaflet

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

1. What CHEMSENTRON is and what it is used for

CHEMSENTRON contains the active substance palonosetron. This belongs to a group of medicines called serotonin (5HT₃) antagonists. CHEMSENTRON is used in adults to help stop you feeling or being sick (nausea and vomiting) when having cancer treatments called chemotherapy. It works by blocking the action of a chemical called serotonin, which can cause you to feel sick or to vomit.



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

CHEMSENTRON should not be administered to you:

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

Warnings and precautions

Tell your doctor or healthcare professional before being given CHEMSENTRON.

Special care with CHEMSENTRON must be taken:

- If you have a blocked bowel or have had repeated constipation in the past
- If you have had heart problems or heart problems run in your family, such as changes in your heartbeat ('QT prolongation')
- If you have an imbalance of certain minerals in your blood which has not been treated - such as potassium and magnesium.

Other medicines and CHEMSENTRON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell them if you are taking the following medicines:

Medicines for depression or anxiety

Tell your doctor or nurse if you are taking any medicines for depression or anxiety, including:

- Medicines called SSRIs ('selective serotonin reuptake inhibitors') – such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- Medicines called SNRIs ('serotonin noradrenaline reuptake inhibitors') – such as venlafaxine, duloxetine (can lead to the development of serotonin syndrome and should be used with caution).



Medicines that can affect your heartbeat

Tell your doctor or nurse if you are taking any medicines that affect your heartbeat as this could cause a heartbeat problem when taken with CHEMSENTRON. This includes:

- Medicines for heart problems such as amiodarone, nicardipine, quinidine.

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 taking this medicine.

CHEMSENTRON should not be used during pregnancy and breastfeeding.

Driving and using machinery

You may feel dizzy or tired after being given CHEMSENTRON. If this happens, do not drive or use any tools or machines.

It is not always possible to predict to what extent CHEMSENTRON may interfere with your daily activities. You should not engage in the above activities until you are aware of the measure to which CHEMSENTRON affects you.

CHEMSENTRON contains sodium

If you are on a salt-free diet. CHEMSENTRON contains less than 1 mmol sodium (23 mg) per vial that is to say essentially 'sodium-free'.

3. How CHEMSENTRON is given

You will not be expected to give yourself CHEMSENTRON. It will be given to you by a person who is qualified to do so. You will be given the medicine about 30 minutes before the start of chemotherapy. The usual dose is 250 micrograms CHEMSENTRON. It is given as an injection into a vein.



If you have been given more CHEMSENTRON than should

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

4. Possible side effects

CHEMSENTRON can have side effects.

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

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects:

- Allergic reaction - the signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing, an itchy, lumpy rash (hives).

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

Other side effects

Tell your doctor if you notice any of the following side effects:

Frequent

- Headache, feeling dizzy
- Constipation, diarrhoea

Less frequent

- Change in the colour of the vein and veins becoming larger
- Feeling happier than usual or feeling anxious
- Feeling sleepy or trouble sleeping



- Decrease or loss of appetite
- Weakness, feeling tired, 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, passing wind (flatulence), dry mouth or indigestion
- Abdominal (stomach) pain
- Difficulty passing water (urinating)
- Joint pain
- High or low blood pressure
- Abnormal heart rate or lack of blood flow to the heart
- 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
- ECG (electrocardiogram) abnormalities ('QT prolongation')
- Burning, pain or redness at the injection site

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 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 CHEMSENTRON.

5. How to store CHEMSENTRON

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the label.

Do not use if you notice that the visual appearance has changed (e.g. if cloudiness or precipitation is observed).

Single use only, any unused solution should be disposed of by returning it to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CHEMSENTRON 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 citric acid monohydrate, disodium edetate, hydrochloric acid (for pH adjustment), mannitol, sodium citrate, sodium hydroxide (for pH adjustment) and water for injections.

What CHEMSENTRON looks like and contents of the pack

CHEMSENTRON solution for injection is a clear, colourless solution and is supplied in a pack of one glass vial with rubber stopper and aluminium cap, which contains 5 ml of the solution.

It is available in packs of 1 vial containing 5 ml of solution.



Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

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This leaflet was last revised in

Registration number

550344

Access to the corresponding Professional Information

To be confirmed

A handwritten signature in black ink, consisting of stylized cursive letters, likely 'Rd'.