Approved Patient Information Leaflet for Medicines for Human Use

KEMOPREV IV

SCHEDULING STATUS: S4

KEMOPREV IV SOLUTION FOR INJECTION

Palonosetron (as Hydrochloride)

Contains sugar (D-Mannitol)

Each 1 mL of KEMOPREV IV solution for injection contains 41,5 mg D-Mannitol per mL

Each KEMOPREV IV 5 mL solution for injection contains 207,5 mg D-Mannitol per vial

Read all of this leaflet carefully before you start taking KEMOPREV IV

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What KEMOPREV IV is and what it is used for

KEMOPREV IV contains the active substance palonosetron (as palonosetron hydrochloride).

Palonosetron 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.

KEMOPREV IV is used for the prevention of nausea and vomiting associated with cancer chemotherapy in adults.

2. What you need to know before you use KEMOPREV IV

KEMOPREV IV should not be administered to you

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

Warnings and precautions

Tell your doctor or health care provider before being given KEMOPREV IV injection

- If you have acute bowel obstruction or a history of repeated constipation
- If you are using KEMOPREV IV in addition to other medicines that may induce an abnormal heart rhythm such as amiodarone, nicardipine, quinidine, haloperidol
- If you or your family suffers from a heart problem called “QT syndrome”
- If you have other heart problems
- If you have low potassium in your blood
- If you have low magnesium in your blood.

It is not recommended to use KEMOPREV IV in the days following chemotherapy unless you are receiving another chemotherapy cycle.

Children and adolescents

Use in patients under 18 years of age is not recommended until further data becomes available.

Other medicines and KEMOPREV IV

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

SSRIs (selective serotonin reuptake inhibitors) medicine used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.

SNRIs (serotonin noradrenaline reuptake inhibitors) medicine 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 health care provider for advice before taking this medicine.

Driving and using machines

KEMOPREV IV may cause dizziness, sleepiness or tiredness if affected, do not drive or use any tools or machines.

3. How to use KEMOPREV IV

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

Adults

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

KEMOPREV IV will be given to you as a slow infusion into a large vein.

Duration of administration

A Healthcare provider will normally inject Palonosetron about 30 minutes before the start of chemotherapy.

Method of administration

KEMOPREV IV is for intravenous use.

If you are given more KEMOPREV IV than you should

Since a health care provider will administer KEMOPREV IV**,** he/she will control the dosage. However, in the event of overdosage your Heath care provider will manage the overdosage.

If you forget to use KEMOPREV IV

Do not receive a double dose to make up for forgotten individual doses.

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

4. Possible side effects

KEMOPREV IV can have side effects.

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

If any of the following happens, stop taking/using KEMOPREV IV and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat
- having difficulty breathing or collapsing
- itchy, lumpy rash (hives)
- burning or pain at the site of injection.

These are very serious side effects. If you have them, you may have had a serious reaction to

KEMOPREV IV. You may need urgent medical attention or hospitalisation.

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

- abnormal heart rate or lack of blood flow to the heart
- electrocardiogram abnormalities (QT prolongation).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness, constipation and diarrhoea.

Less frequent side effects:

- high or low blood pressure
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your Heath care provider.

Reporting of side effects

If you get side effects, talk to your doctor. 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 KEMOPREV IV**.**

5. How to store KEMOPREV IV

Your doctor knows how to store KEMOPREV IV**.** The Heath care provider who is administering KEMOPREV IV to you, will make sure that the medicine is not used after the expiry date printed on the vial.

Store at or below 25 °C.

They will also reconstitute KEMOPREV IV and visually inspect the solution before giving it to you. Only clear solution without particles will be used.

6. Contents of the pack and other information

What KEMOPREV IV contains

- The active substance is palonosetron hydrochloride

The other ingredients are Citric acid monohydrate, D-Mannitol, Edetate disodium dihydrate,

Trisodium dihydrate citrate

Reconstituted solution:

The solution is clear and varies from colourless to yellow depending on the concentration. The solution is free of any visible particles.

What KEMOPREV IV looks like and contents of the pack

KEMOPREV IV is presented in type I transparent glass vial with 8 mL capacity with a chlorobutyl siliconised fluorotec rubber stopper and aluminium cap with polypropylene top, with self-adhesive identification label, packed into a cardboard carton and a leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

This leaflet was last revised in

21 February 2023

Registration number

53/5.10/0647