

1.3.2 Patient Information Leaflet

**SCHEDULING STATUS**

S4

**OXALIPLATIN KEY 50 (powder for injection)**

**OXALIPLATIN KEY 100 (powder for injection)**

**Oxaliplatin**

**OXALIPLATIN KEY 50 contains sugar: Mannitol 200 mg**

**OXALIPLATIN KEY 100 contains sugar: Mannitol 400 mg**

**Please read all of this leaflet carefully before you start treatment with OXALIPLATIN**

**KEY**

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

**1. What OXALIPLATIN KEY is and what it is used for**

**What OXALIPLATIN KEY is:**

### 1.3.2 Patient Information Leaflet

Oxaliplatin belongs to the group of medicines called antineoplastics. This medicine interferes with the growth of cancer cells to eventually destroy the cancer cells and is used in combination with other anticancer medicines.

#### **What it is used for:**

- Treatment of advanced large bowel (colon) or back passage (rectum) cancer;
- Additional treatment of large bowel (colon) cancer.

## **2. What you need to know before you are given OXALIPLATIN KEY**

#### **OXALIPLATIN KEY should not be administered to you:**

- if you are hypersensitive (allergic) to oxaliplatin or any of the other ingredients of oxaliplatin key (listed in section 6);
- if you suffer from severe kidney disease;
- if you are pregnant or breastfeeding;
- if you suffer from bone marrow failure or suppression;
- if you already have tingling and numbness in the fingers and/or toes, and have difficulty performing delicate tasks, such as buttoning clothes. You may be suffering from a disease that damages the nerves, called peripheral sensory neuropathy;
- if you already have reduced number of blood cells (white blood cells and/or platelets);
- if you have damage to the lungs.

#### **Warnings and precautions**

#### **Tell your doctor or healthcare provider before being given the infusion:**

- if you have a history of allergic reactions to any other platinum containing medicines, such as carboplatin, cisplatin etc.;

### 1.3.2 Patient Information Leaflet

- if you have moderate kidney disease;
- if you have nerve damage (neuropathy);
- if you have any liver problems or disease;
- if your blood cell counts are too low after previous treatment. Your doctor will perform tests to check that you have sufficient blood cells before treatment;
- if you are pregnant, breastfeeding or planning a pregnancy. It is not recommended that you become pregnant during treatment with OXALIPLATIN KEY and you must use an effective method of contraception. Potentially fertile patients should take appropriate contraceptive measures during and after stopping therapy, continuing for 4 months in women and 6 months in men;
- OXALIPLATIN KEY may have an antifertility effect, which may be irreversible. Male patients are therefore advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment;
- if you have or had heart disorders such as an abnormal electrical signal called prolongation of the QT interval, an irregular heartbeat, or a family history of heart problems.

Don't have immunisations with live vaccines while you're having treatment. Ask your doctor or pharmacist how long you should avoid live vaccinations. You can have other vaccines, but they might not give you as much protection as usual.

If any of the following applies to you at any time, tell your doctor immediately. Your doctor may need to treat you for these events.

Alternatively, your doctor may need to reduce the dose of OXALIPLATIN KEY or delay or stop your treatment with OXALIPLATIN KEY (see section 4):

### 1.3.2 Patient Information Leaflet

- if you notice the following symptoms: rash or itching, swelling of the face, lips, mouth, throat or other parts of your body, which may cause difficulty in swallowing or breathing (see section 4). You may have a serious allergic reaction to OXALIPLATIN KEY that may need immediate medical attention;
- if you notice a sensation of discomfort or pain close to or at the injection site during the infusion (possible leakage into the surrounding tissue). Your healthcare professional must stop treatment immediately and initiate treatment of local symptoms (see section 3);
- if you have symptoms of nerve damage such as weakness, numbness, disturbances of feeling or taste after previous OXALIPLATIN KEY treatment. These effects are often triggered by exposure to cold. If you notice such symptoms tell your doctor, especially if they are troublesome and/or last longer than 7 days. Your doctor will carry out neurological examinations, before and regularly during OXALIPLATIN KEY treatment, especially if you are given other medicines which may cause nerve damage. Symptoms of nerve damage can persist after the end of the OXALIPLATIN KEY treatment;
- if you experience numbness or tingling in your fingers or toes. These symptoms can persist in some patients after the end of the treatment and may not be reversible. Your doctor will perform a neurological examination regularly, especially if other medicines are co-administered which affect the nerves;
- if you experience symptoms such as headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss (symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder). It may influence your ability to drive and use machines (see Driving and using machines) and your doctor may decide to do additional brain imaging tests;

### 1.3.2 Patient Information Leaflet

- if you experience persistent or severe diarrhoea, nausea (feel sick) or vomiting (being sick). In addition, abdominal (tummy) pain, bloody diarrhoea (dark coloured /tarry stools) and bloody vomit (vomit that looks like “coffee grounds”) may be caused by a reduction of blood flow to your gut wall (intestinal ischaemia) or a stomach or intestinal ulcer that may require immediate medical attention;
- if you have signs of infection such as a sore throat and high temperature (a single temperature of > 38,3 °C or a sustained temperature of > 38 °C for more than one hour), particularly if associated by persistent diarrhoea. You may be at risk of getting an infection of the blood which could be very serious and needs immediate attention. OXALIPLATIN KEY can also cause a reduction of the number of blood cells, your doctor will check your blood frequently;
- if you experience sore lips or mouth ulcers. Your doctor might decide to delay your next treatment depending on your blood results;
- if you experience unexplained respiratory symptoms such as a non-productive cough, difficulty in breathing or crackles;
- if you experience unexpected bleeding or bruising (disseminated intravascular coagulation), tell your doctor as these could be signs of blood clots throughout the small vessels of your body and may require immediate medical attention;
- if you have chest pain, an uncomfortable feeling or pressure in the chest (these could be symptoms of a heart attack or a serious heart problem);
- if you develop an extreme tiredness, shortness of breath, or kidney disease where you pass little or no urine (symptoms of acute renal failure);
- if you faint (lose consciousness) or have an irregular heartbeat or palpitations, tell your doctor immediately as this may be a sign of a serious heart condition;

### 1.3.2 Patient Information Leaflet

- if you experience muscle pain and swelling, in combination with weakness, fever, or red-brown urine. These could be signs of muscle damage (rhabdomyolysis) and could lead to kidney problems or other complications.

It is very important that your doctor check your progress at regular visits to make sure that OXALIPLATIN KEY is working properly and to check for unwanted effects. Some of the side effects of OXALIPLATIN KEY do not have any symptoms and must be found with a blood test.

OXALIPLATIN KEY should only be used in specialised cancer departments and under the supervision of a doctor that specialises in cancer treatment.

OXALIPLATIN KEY can temporarily lower the number of white blood cells in your blood, increasing the chance of getting an infection. It can also lower the number of platelets, which are needed for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:

- Try to avoid people with infections.
- Be careful when using a regular toothbrush, dental floss or toothpick so not to start bleeding.
- Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime.
- Be careful not to cut yourself when you are using a sharp object such as a razor or fingernail or toenail cutters.
- Avoid contact sports or other situations where bruising or injury could occur.

### 1.3.2 Patient Information Leaflet

#### **Children**

Do not give OXALIPLATIN KEY to children.

#### **Other medicines and OXALIPLATIN KEY**

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

Tell your doctor if you are taking any of the following medicines:

- If you also receive other anticancer medicines, the risk of diarrhoea, vomiting, sore mouth and blood abnormalities is increased.
- Bone marrow depressants and radiation used together with OXALIPLATIN KEY may cause an increase in bone marrow depression and gastrointestinal side effects.
- The use of live virus vaccines together with OXALIPLATIN KEY may decrease your antibody response to the vaccine. Immunisation should be discussed with your medical practitioner before therapy starts.
- Anticoagulants (medicines like warfarin or heparin that prevent your blood from forming clots).
- Medicines known to prolong the QT interval (abnormal electrical signal of the heart), such as quinidine, disopyramide, amiodarone, sotalol, dofetilide and ibutilide.
- Medicines known to be associated with rhabdomyolysis (muscle damage) such as statins, antipsychotics, zidovudine, colchicine, selective serotonin reuptake inhibitors and lithium (see section 2, Warnings and precautions).

#### **OXALIPLATIN KEY with food and drink and alcohol**

The use of cold drinks during infusion of OXALIPLATIN KEY should be avoided, because cold temperature can make symptoms that affect nerves for example tingling and/or

### 1.3.2 Patient Information Leaflet

numbness in the fingers toes, around the mouth or in the throat, worse. Avoid eating foods that may make nausea worse, such as fatty, fried or spicy foods.

#### **Pregnancy and breastfeeding and fertility**

You should not receive OXALIPLATIN KEY if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking OXALIPLATIN KEY.

Effective birth control to prevent pregnancy is advised during OXALIPLATIN KEY treatment and after the end of OXALIPLATIN KEY treatment for the following 4 months for women and for 6 months for men.

OXALIPLATIN KEY may have an anti-fertility effect which could be irreversible. Men treated with OXALIPLATIN KEY are therefore advised not to father a child during and up to 6 months after OXALIPLATIN KEY treatment and to seek advice on conservation of sperm prior to OXALIPLATIN KEY treatment.

#### **Driving and using machinery**

It is not always possible to predict to what extent OXALIPLATIN KEY may interfere with the daily activities of a patient.

OXALIPLATIN KEY treatment may result in an increased risk of vision problems, dizziness, nausea, vomiting and other neurological symptoms that affect walking and balance. If this happens you should not drive, operate machines or engage in dangerous activities.

### 1.3.2 Patient Information Leaflet

#### **OXALIPLATIN KEY contains mannitol**

OXALIPLATIN KEY contains mannitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told that you have an intolerance to some sugars, you should not receive OXALIPLATIN KEY.

### **3. How to receive OXALIPLATIN KEY**

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

**OXALIPLATIN KEY should only be used in specialised departments of oncology and administered under the supervision of an experienced oncologist.**

The usual dose is:

#### **FOR ADULTS ONLY:**

- OXALIPLATIN KEY will be administered intravenously by your doctor or under his supervision.
- Your doctor will determine the exact dosage that you will need.  
The dosage may vary according to the type of cancer that you have.
- The recommended dose is administered intravenously over 2 to 6 hours and usually repeated every two weeks.
- Your doctor will tell you how long your treatment with OXALIPLATIN KEY will last.
- If you have the impression that the effect of OXALIPLATIN KEY is too strong or too weak, tell your doctor or pharmacist.
- You will not be expected to give yourself OXALIPLATIN KEY. It will be given to you by a person who is qualified to do so.

### 1.3.2 Patient Information Leaflet

#### **Patients with kidney disease:**

- Your dose may be adjusted if you suffer from moderate kidney disease.

#### **Patients with liver disease:**

- No dosage adjustment is necessary if you have liver disease.

#### **Elderly patients:**

- No dosage adjustment is necessary for elderly patients.

#### **Paediatric Use:**

- The safety and effectiveness of OXALIPLATIN KEY in children have not been established.

#### **If you receive more OXALIPLATIN KEY than you should**

Since a healthcare professional will administer OXALIPLATIN KEY, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

#### **If you missed a dose of OXALIPLATIN KEY**

Since a healthcare provider will administer OXALIPLATIN KEY, it is unlikely that the dose will be missed.

OXALIPLATIN KEY needs to be given on a fixed schedule. Be sure to keep all appointments. If you miss a dose, you should discuss this with your medical practitioner. Your doctor will decide when you should be given your next dose of OXALIPLATIN KEY.

### 1.3.2 Patient Information Leaflet

#### **If you stop receiving OXALIPLATIN KEY**

Stopping your treatment with OXALIPLATIN KEY may stop the effect on tumour growth. Do not stop the treatment with OXALIPLATIN KEY unless you have discussed this with your medical practitioner. If you have any further question on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

OXALIPLATIN KEY can have side effects.

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

**If any of the following happens, stop receiving OXALIPLATIN KEY and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- serious infection of the blood in addition to a reduction in white blood cells (neutropenic sepsis), which may be fatal,
- reduction in white blood cells accompanied by fever > 38.3 °C or a prolonged fever > 38 °C for more than one hour (febrile neutropenia),
- pain in the chest or upper back, difficulty breathing and coughing up blood (symptoms of clots in the lungs),

### 1.3.2 Patient Information Leaflet

- unexpected bleeding or bruising due to widespread blood clots throughout the small blood vessels of the body (disseminated intravascular coagulation), which may be fatal. Blood clots, usually in the leg, which can cause pain, swelling or redness,
- headache, altered mental functioning, seizures (fits) and abnormal vision from blurriness to vision loss (symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder),
- scarring and thickening in the lungs with difficulties in breathing, sometimes fatal (interstitial lung disease),
- serious infection of the blood and low blood pressure (septic shock), which may be fatal,
- kidney disease where you pass little or no urine (symptoms of Haemolytic-uraemic syndrome),
- stroke symptoms (including sudden severe headache, confusion, trouble seeing in one or both eyes, numbness or weakness of face, arm or leg usually on one side, face drooping, trouble walking, dizziness, loss of balance and speech difficulty),
- abnormal heart rhythm (QT prolongation), that can be seen on electrocardiogram (ECG), which may be fatal,
- pneumonia (serious lung infection) which may be fatal,
- abdominal pain, nausea, bloody vomit or vomit that looks like "coffee grounds", or dark coloured/ tarry stools (symptoms of gastrointestinal ulcer, with potential bleeding or perforation), which may be fatal,
- decreased blood flow to the intestine/bowel (intestinal ischaemia), which may be fatal,
- muscle pain and swelling, in combination with weakness, fever, or red-brown urine (symptoms of muscle damage called rhabdomyolysis), which may be fatal.

### 1.3.2 Patient Information Leaflet

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to OXALIPLATIN KEY. 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 bruising, bleeding or signs of infection such as a sore throat and high temperature,
- persistent or severe diarrhoea or vomiting,
- sore lips or mouth ulcers (stomatitis/mucositis),
- unexplained symptoms affecting your breathing system, such as non-productive cough, breathing difficulties,
- effects on the nerves (peripheral sensory neuropathy). you may feel a tingling and/or numbness in the fingers, toes, around the mouth or in the throat, which may sometimes occur in association with cramps. This side effect is often triggered by exposure to cold e.g. opening a refrigerator or holding a cold drink,
- you may also have difficulty in performing delicate tasks, such as buttoning clothes,
- some people have experienced a tingling shock-like sensation passing down the arms or trunk when the neck is flexed,
- OXALIPLATIN KEY can sometimes cause an unpleasant sensation in the throat, in particular when swallowing, and give the sensation of shortness of breath. This sensation, if it happens, usually occurs during or within hours of the infusion and may be triggered by exposure to the cold,

### 1.3.2 Patient Information Leaflet

- decreased number of red blood cells, which may make the skin pale, and cause weakness or breathlessness. Your doctor will take blood to check that you have sufficient blood cells before you start treatment and before each subsequent course,
- blood abnormality (lack of platelets) caused by an allergic reaction associated with bruises and abnormal bleeding (immunoallergic thrombocytopenia),

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

#### **Tell your doctor if you notice any of the following:**

The following side effects have been reported frequently:

- loss or lack of appetite,
- high levels of glucose (blood sugar) in your blood, which may cause thirst, dry mouth and frequent urination,
- low levels of potassium in your blood, which may cause abnormal heartbeat,
- low levels of sodium in your blood, which may cause fatigue and confusion, muscular jerking, cramps or coma,
- taste alterations,
- headache,
- nose bleeds,
- breathlessness,
- cough,
- nausea (feeling sick) and vomiting (being sick),
- stomach pain, constipation,
- blockage or swelling of the bowel,
- skin disorder,

### 1.3.2 Patient Information Leaflet

- hair loss,
- back pain,
- fatigue, weakness and pain,
- reaction close to or at the injection site during the infusion (local pain, redness, swelling of skin, hardening of skin, death of skin tissue),
- alteration in blood tests including those relating to abnormalities in liver function,
- weight increase,
- rigors (tremors),
- runny nose (rhinitis),
- upper respiratory tract infection,
- dehydration,
- depression, sleeplessness,
- dizziness,
- swelling of the nerves to the muscles,
- rigidity, intolerance of bright light and headache (meningism),
- inflammation of the conjunctiva, abnormal vision,
- abnormal bleeding, blood in the urine/stools,
- flushing,
- hiccups, chest pain,
- indigestion and heart burn,
- flaking skin, skin rash, increased sweating and nail disorders,
- joint pain and bone pain,
- pain on passing urine and changes in the frequency of urination,
- alteration in blood test which measures the kidney function,

### 1.3.2 Patient Information Leaflet

- weight decrease,
- tightness of the chest caused by cramp of the respiratory tract muscles (bronchospasm),
- blood test which indicates increased acidity in the blood,
- hearing problems,
- eye disorders such as drooping of the upper eye lid, and double vision,
- loss or impairment of the voice, roughness of the voice (hoarseness),
- abnormal tongue sensation, difficulty speaking,
- facial pain and/or eye pain,
- slurred speech,
- lack of red blood cells caused by too much degradation of blood (haemolytic anaemia),
- liver disease.

The following side effects have been reported less frequently:

- nervousness,
- reduction in visual acuity, disturbance of the visual field, inflammation of the optic nerve (optic neuritis),
- deafness,
- jaw spasms, muscle spasms, involuntary muscle contractions, muscle twitching,
- unexplained symptoms affecting your breathing system, such as non-productive cough, breathing difficulties,
- inflammation of the large bowel, which may cause abdominal pain or diarrhoea (colitis),

### 1.3.2 Patient Information Leaflet

- kidney inflammation and kidney failure.

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

#### **Reporting of side effects**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions 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 OXALIPLATIN KEY.

#### **5. How to store OXALIPLATIN KEY**

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package/container.

Keep the container in the outer carton.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/carton/bottle.

Return all unused medicine to your pharmacist.

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

### 1.3.2 Patient Information Leaflet

## **6. Contents of the pack and other information**

### **What OXALIPLATIN KEY contains:**

The active substance is:

Each OXALIPLATIN KEY 50 vial contains 50 mg oxaliplatin

Each OXALIPLATIN KEY 100 vial contains 100 mg oxaliplatin

The other ingredients are:

Mannitol

Water for injection

### **What OXALIPLATIN KEY looks like and contents of the pack:**

#### **What OXALIPLATIN KEY looks like:**

Well-formed white cake free from foreign particles.

#### **Contents of the pack:**

The freeze-dried product is packed in a Type I transparent glass vial, with a grey bromobutyl stopper and a red flip-off cap.

### **Holder of Certificate of Registration and Manufacturer**

Key Oncologics (Pty) Ltd

39 – 11<sup>th</sup> Avenue

Houghton Estate, Johannesburg

South Africa

### 1.3.2 Patient Information Leaflet

**This leaflet was last revised in**

Date of publication: 26 November 2015

Date of revision of text: 19 April 2024

**Registration number**

OXALIPLATIN KEY 50: 45/26/0330

OXALIPLATIN KEY 100: 45/26/0331

**Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website.