PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

OXALIPLATIN 50 mg/10 ml FRESENIUS

OXALIPLATIN 100 mg/20 ml FRESENIUS

Concentrate for Solution for Infusion

Sugar Free

***Read all of this leaflet carefully before you start using O*XALIPLATIN FRESENIUS**

- *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 **OXALIPLATIN FRESENIUS** is and what it is used for

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

3. How **OXALIPLATIN FRESENIUS** is given to you

4. Possible side effects

5. How to store **OXALIPLATIN FRESENIUS**

6. Contents of the pack and other information

1. What OXALIPLATIN FRESENIUS is and what it is used for

OXALIPLATIN FRESENIUS contains oxaliplatin, which is one group of medicines known as antineoplastic, or anticancer medicine and contains platinum.

Oxaliplatin is used to treat cancer of the large bowel. Oxaliplatin is used in combination with other anticancer medicines called 5-fluorouracil and folinic acid.

2. What you need to know before you are given OXALIPLATIN FRESENIUS

Do not use OXALIPLATIN FRESENIUS:

- if you are hypersensitive (allergic) to oxaliplatin or any of the other ingredients of **OXALIPLATIN FRESENIUS** (listed in section 6).

- if you are breastfeeding.
- if you already have a reduced number of blood cells.
- if you already have tingling and numbness in the fingers and/or toes, and have difficulty performing delicate tasks, such as buttoning clothes.
- if you have severe kidney problems.

Warnings and precautions

Only experienced doctor or healthcare provider in cancer therapy should provide you with treatment.

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with **OXALIPLATIN FRESENIUS:**

- if you have mild or moderate kidney problems.
- if you have ever suffered an allergic reaction to platinum-containing medicines such as carboplatin, cisplatin. Allergic reactions can occur during any **OXALIPLATIN FRESENIUS** infusion. Unintentional injection into the tissue outside blood vessels (extravasation) may cause local tissue damage. Your doctor will treat this.
- if you have an unpleasant sensation in the throat, in particular when swallowing, and have a sensation of shortness of breath, during the treatment.
- if you have nerve problems in your hands or feet, such as numbness or tingling, or decreased sensations in your hands or feet.
- if you have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss.
- if you feel or are sick (nausea or vomiting), tell your doctor.
- if you have severe diarrhoea.
- if you have sore lips or mouth ulcers (mucositis/stomatitis).
- if you have diarrhoea, or a reduction in white blood cells or platelets. Your doctor may reduce the dose of **OXALIPLATIN FRESENIUS** or postpone your treatment with **OXALIPLATIN FRESENIUS.**
- if you have fever (temperature greater than or equal to 38 °C), or chills, which could be signs of infection. You may be at risk of getting an infection of the blood.
- if you have temperature > 38 °C. Your doctor may determine you also have a reduction in white blood cells.
- if you have unexplained respiratory symptoms such as cough, or any difficulties in breathing. Your doctor may stop your treatment with **OXALIPLATIN FRESENIUS**.
- 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 experience unexpected bleeding or bruising (disseminated intravascular coagulation), these could be signs of blood clots throughout the small vessels of your body.
- 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.
- 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.
- if you have abdominal pain, nausea, bloody vomit or vomit that looks like “coffee-grounds”, or dark-coloured/ tarry stools, which may be signs of an ulcer of the bowel (gastrointestinal ulcer, with potential bleeding or perforation).
- if you have any liver problems or abnormal liver function test results during your treatment.

Children and adolescents

OXALIPLATIN FRESENIUS is indicated for adults only.

Other medicines and OXALIPLATIN FRESENIUS:

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

Caution is advised when **OXALIPLATIN FRESENIUS** treatment is given together with medicines that are:

- known to cause QT prolongation (an irregular heartbeat).
- known to be associated with rhabdomyolysis (muscle damage).

OXALIPLATIN FRESENIUS with food, drink and alcohol

None known.

Pregnancy and 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 healthcare provider for advice before taking this medicine.

Pregnancy

- It is not recommended that you become pregnant during treatment with **OXALIPLATIN FRESENIUS** and must use an effective method of contraception. Female patients should take appropriate contraceptive measures during and after cessation of therapy continuing for 4 months.
- If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor before you receive any treatment.
- If you get pregnant during your treatment, you must immediately inform your doctor.

Breastfeeding

- You must not breastfeed while you are treated with **OXALIPLATIN FRESENIUS.**

Fertility

- **OXALIPLATIN FRESENIUS** may have an anti-fertility effect, which could be irreversible. Male patients should seek advice on conservation of sperm prior to treatment.

- Male patients are advised not to father a child during treatment and until 6 months after treatment, and to take appropriate contraceptive measures during this time.

Driving and using machines

It is not always possible to predict to what **extent OXALIPLATIN FRESENIUS** 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 **OXALIPLATIN FRESENIUS** affects them.

Oxaliplatin treatment may result in an increased risk of dizziness, nausea and vomiting, and other neurologic symptoms that affect walking and balance. If this happens, you should not drive or operate machinery. If you have vision problems while taking OXALIPLATIN FRESENIUS, do not drive, operate machines, or engage in dangerous activities.

OXALIPLATIN FRESENIUS contains water for injection.

3. How OXALIPLATIN FRESENIUS is given to you

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

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

OXALIPLATIN FRESENIUS is intended only for adults.

OXALIPLATIN FRESENIUS is for single use only.

Recommended Dose

The dose of **OXALIPLATIN FRESENIUS** is based on your body surface area.

This is calculated from your height and weight.

The usual dose for adults including the elderly is 85 mg/m^2 of body surface area. The dose you receive will also depend on results of blood tests and whether you have previously experienced side effects with **OXALIPLATIN FRESENIUS**.

Method and route of administration

- You will be treated by a healthcare professional trained in cancer treatment, who will have made up the required dose of **OXALIPLATIN FRESENIUS**.

- **OXALIPLATIN FRESENIUS** is given by slow injection into one of your veins (an intravenous infusion) over a 2 to 6 hour period.
- **OXALIPLATIN FRESENIUS** will be given to you before that of folinic acid and of 5-fluorouracil.

Frequency of administration

You should usually receive your infusion once every 2 weeks.

Duration of treatment

The duration of treatment will be determined by your doctor.

Your treatment will last a maximum of 6 months.

If you use more OXALIPLATIN FRESENIUS than you should

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

If you forget to use OXALIPLATIN FRESENIUS

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

4. Possible side effects

OXALIPLATIN FRESENIUS can have side effects.

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

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

- symptoms of an allergic or anaphylactic reaction with sudden signs such as rash, itching or hives on the skin, difficulties in swallowing, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, extreme tiredness (you may feel you are going

to faint), In the majority of cases, these symptoms occurred during the infusion or immediately after but delayed allergic reactions have also been observed hours or even days after the infusion.

- abnormal bruising, bleeding or signs of infection such as a sore throat and high temperature.
- Infection to the blood (sepsis), with symptoms of fever and chills, very low body temperature, urinating less than normal, rapid pulse, rapid breathing, nausea and vomiting, diarrhoea, body aches.
- presence of blood or dark brown coffee-coloured particles in your vomit, abdominal pain, blood in your stool (symptoms of gastrointestinal hemorrhage).
- stomatitis/mucositis (sore lips or mouth ulcers).
- respiratory symptoms such as dry cough or wet cough, difficulties in breathing or crackles, shortness of breath and wheezing as these may be indicators of a serious lung disease that may lead to death.
- a group of 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).
- abnormal bleeding.
- infection due to a reduction in white blood cells.
- serious infection of the blood in addition to a reduction in white blood cells (neutropenic sepsis), which may be fatal.
- blood in the urine/stools, swelling of the veins, clots in the lung.
- blockage or swelling of the bowel.
- scarring and thickening in the lungs with difficulties in breathing, sometimes fatal (interstitial lung disease).
- unexpected bleeding or bruising due to widespread blood clots throughout the small blood vessels of the body (disseminated intravascular coagulation), which may be fatal.
- abnormal heart rhythm (QT prolongation), that can be seen on electrocardiogram (ECG), which may be fatal.
- extreme tiredness with decreased number of red blood cells, and shortness of breath (haemolytic anaemia), alone or combined with low platelet count and kidney disease where you pass little or

no urine, (symptoms of Haemolytic-uraemic syndrome), which may be fatal have been reported.

- muscle pain and swelling, in combination with weakness, fever, or red-brown urine (symptoms of muscle damage called rhabdomyolysis), which may be fatal.
- decreased blood flow to the intestine/bowel (intestinal ischemia), which may be fatal.
- risk of new cancers, Leukaemia, a form of blood cancer, has been reported in patients after taking oxaliplatin in combination with certain other medicines. Talk to your doctor about the potential for increased risk of this type of cancer when taking oxaliplatin and certain other medicines.

These are all very serious side effects. If you have them, you may have had a serious reaction to **OXALIPLATIN FRESENIUS**. 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:

- a tingling and/or numbness in the fingers, toes, around the mouth or in the throat, which may sometimes occur in association with cramps.

  These effects are 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 (peripheral neuropathy). Although in the majority of cases these symptoms resolve themselves completely there is a possibility of persistent symptoms of peripheral sensory neuropathy after the end of the treatment.

  Some people have experienced a tingling, shock-like sensation passing down the arms or trunk when the neck is flexed.
- reduction in the number of blood cells. The reduction of red cells may cause anaemia (a reduction of red cells), abnormal bleeding or bruising (due to a reduction in platelets). The reduction in white blood cells may make you prone to infections. Your doctor will take blood to check that you have sufficient blood cells before you start treatment and before each subsequent course.
- swelling of the nerves to your muscles, neck stiffness, abnormal tongue sensation possibly altering speech.
- alteration in blood tests including those relating to abnormalities in liver function.
- reduction in white blood cells accompanied by temperature > 38,3 °C or a prolonged temperature > 38 °C for more than one hour (febrile neutropenia).

- lung disorders.
- pain on passing urine and changes in kidney function, changes of frequency of urination, dehydration.
- high blood pressure.

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:

- 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, although unpleasant, it will not last long and goes away without the need for any treatment.

  Your doctor may decide to alter your treatment as a result.
- diarrhoea, mild nausea (feeling sick) and vomiting (being sick); however medication to prevent the sickness is usually given to you by your doctor before treatment and may be continued after treatment.
- sensation of discomfort close to or at the injection site during the infusion.
- fever, rigors (tremors), mild or severe tiredness, body pain.
- weight changes, loss or lack of appetite, taste disorders, constipation.
- headache, back pain.
- stomach pain.
- coughing, difficulty in breathing.
- mild hair loss (alopecia).
- indigestion and heartburn, hiccups, flushing, dizziness.
- increased sweating and nail disorders, flaking skin.
- runny nose.
- joint pain and bone pain.
- depression and insomnia.
- conjunctivitis, visual problems.
- decreased levels of calcium in the blood.

Less frequent side effects:

- loss of hearing.
- reversible short-term loss of vision.

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. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: : http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **OXALIPLATIN FRESENIUS**.

You should also report side effects to the Holder of Certificate of Registration, **Fresenius Kabi South Africa (Pty) Limited.**

The contact details for our national reporting system are:

Email: safety.fksa@fresenius-kabi.com

Tel: +27 11 545 0000

Emergency: 0860 203 900

5. How to store OXALIPLATIN FRESENIUS

Store all medicines out of reach of children.

- Hospital staff will store your medicine safely:
    - Store at or below 25 °C. Do not freeze.
    - **After dilution,** once opened the product may be stored for 24 hours at room temperature (15 °C -25 °C) and at refrigerated condition (2 °C -8 °C).
    - Store in the original container.
    - Keep the container in the outer carton.
    - Keep the container tightly closed.
- Do not use after the expiry date stated on the label and carton.
- Do not use **OXALIPLATIN FRESENIUS** if you notice that the solution is not clear and free of

particles.

- Return all unused medicine 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 OXALIPLATIN FRESENIUS contains

- The active substance is oxaliplatin.

  One ml of concentrate for solution for infusion contains 5 mg oxaliplatin:

  OXALIPLATIN FRESENIUS is available as:

  OXALIPLATIN 50 mg/10 ml FRESENIUS: Each vial contains 10 ml of concentrate for solution for infusion equivalent to 50 mg oxaliplatin.

  OXALIPLATIN 100 mg/20 ml FRESENIUS: Each vial contains 20 ml of concentrate for solution for infusion equivalent to 100 mg oxaliplatin.
- The other ingredient is water for injection.

What OXALIPLATIN FRESENIUS looks like and contents of the pack

Clear, colourless solution, free from visible particles.

OXALIPLATIN 50 mg/10 ml FRESENIUS: 10 ml concentrate in a vial (clear tubular glass) with Flurotec elastomeric stopper and green aluminium flip- off overseal.

OXALIPLATIN 100 mg/20 ml FRESENIUS: 20 ml concentrate in a vial (clear tubular glass) with Flurotec elastomeric stopper and blue aluminium flip-off overseal.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Limited

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