Patient Information Leaflet

SCHEDULING STATUS: S4

Eloplat® 50 (concentrate for solution for infusion)

Eloplat® 100 (concentrate for solution for infusion)

Eloplat® 150 (concentrate for solution for infusion)

Eloplat® 200 (concentrate for solution for infusion)

Oxaliplatin

Sugar free.

Read all of this leaflet carefully before ELOPLAT is administered to you.

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

WHAT IS IN THIS LEAFLET

1. What ELOPLAT is and what it is used for

2. What you need to know before you receive ELOPLAT

3. How to use ELOPLAT

4. Possible side effects

5. How to store ELOPLAT

6. Contents of the pack and other information

1. WHAT ELOPLAT IS AND WHAT IT IS USED FOR

The active substance of ELOPLAT is oxaliplatin.

Oxaliplatin belongs to a group of medicines called antineoplastics.

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Oxaliplatin is an anti-cancer medicine and is used to treat metastatic (advanced) cancer of the colon (large bowel) or rectum (back passage), or as additional treatment following surgery to remove a tumour (growth) in the colon.

It is used in combination with other anti-cancer medicines called 5-fluorouracil (5-FU) and folinic acid (FA).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ELOPLAT

ELOPLAT should not be administered to you:

- If you are allergic (hypersensitive) to oxaliplatin or any of the ingredients of ELOPLAT (see "WHAT ELOPLAT CONTAINS").
- If you are pregnant or 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 a severe kidney problem.

Warnings and precautions

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

- If you have moderate kidney problems.
- If you have ever suffered an allergic reaction to other platinum-containing medicines such as carboplatin or cisplatin.
- If you have symptoms of nerve damage such as weakness, numbness or disturbance of feeling after previous ELOPLAT 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 regularly carry out neurological examinations, before and regularly during treatment, especially if you are given other medicines which may cause nerve damage.

- If you have any lung diseases.
- If you have any liver problems.
- If your blood cell counts are too low after previous infusions of ELOPLAT. Your doctor will regularly take blood to check you have sufficient blood cells.
- Before and/or during treatment with ELOPLAT you may be given special medicines to prevent and/or treat vomiting.
- If you are received any vaccines or plan to receive any vaccines. During treatment with ELOPLAT, you should not have a vaccination with "live" or "attenuated" vaccines, such as yellow fever vaccine.
- 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.

Other medicines with ELOPLAT:

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

The following medicines cause an interaction when used in combination with ELOPLAT:

- Erythromycin, an antibiotic used to treat bacterial infections.
- Salicylates which are chemicals found in plants and are a major ingredient in aspirin and other pain-relieving medicines.
- Granisetron, an antiemetic used to treat nausea and vomiting.
- Paclitaxel, an anti-cancer medicine used to treat breast cancer.
- Sodium valproate, an anticonvulsant used to treat epilepsy.
- Prolong the QT interval (abnormal electrical signal of the heart), such as quinidine, disopyramide, amiodarone, sotalol, dofetilide and ibutilide.

- Statins, antipsychotics, known to be associated with rhabdomyolysis (muscle damage) such as zidovudine, colchicine, selective serotonin reuptake inhibitors and lithium.

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 other health care provider for advice before taking this medicine.

Pregnancy:

You must not become pregnant during treatment with ELOPLAT and must use an effective method of contraception. If pregnancy occurs during your treatment, you must immediately inform your doctor. You should take appropriate contraceptive measures during and after cessation of therapy continuing for 4 months for women and 6 months for men.

Breastfeeding:

ELOPLAT must not be administered to you if you are pregnant or breastfeeding.

Fertility:

ELOPLAT may have an anti-fertility effect, which could 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.

Driving and using machines:

- ELOPLAT may cause dizziness, nausea and vomiting, and other neurological symptoms that affect gait and balance.
- Do not drive because ELOPLAT could interfere with your ability to drive safely.
- Do not operate any tools or machines while using ELOPLAT

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3. HOW TO USE ELOPLAT

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

ELOPLAT is given as an injection or infusion into a vein.

If you have the impression that the effect of ELOPLAT is too strong or too weak, tell your doctor or pharmacist.

Dosage:

The dose depends on your body surface area (calculated by m^2) and your state of health. It also depends on other medicines that are used in your cancer treatment. 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 ELOPLAT.

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Method and route of administration

ELOPLAT will be prescribed for you by a specialist in cancer treatment.

You will be treated by a healthcare professional, who will have made up the required dose of ELOPLAT.

ELOPLA Twill be given by slow intravenous infusion (drip) into one of your veins over a 2 to 6 hour period.

ELOPLAT will be given to you at the same time as folinic acid and before the infusion 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. Treatment for 6 months is recommended when ELOPLAT is used after surgery to remove your cancer.

If you receive more ELOPLAT than you should:

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

If you forget to use ELOPLAT

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

4. POSSIBLE SIDE EFFECTS

ELOPLAT can have side effects.

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

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

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

- Allergic reactions causing swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

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

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

- Low blood pressure (feeling faint).
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, dark coloured urine, signs of hepatitis and liver damage.
- Haemolytic anaemia resulting from the destruction of red blood cells, tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes.
- Chest pain.
- Blood clots.
- Inflammation of the veins.
- Leg pain or swelling due to blood clot signs of deep vein thrombosis.
- Rectum bleeding.
- High blood pressure.
- Cough, chest pain, shortness of breath signs of thromboembolic events.
- Serious blood condition resulting in bacteria in the blood.
- Low number of platelets in the blood causing bleeding into the tissues, bruising, and slow blood clotting after injury (signs of thrombocytopenia).
- Damage or inflammation of the nerves causing abnormal sense of touch or pins and needles.
- Fits.

- Neck stiffness, intolerance of bright light and headache (signs of meningism).
- Loss of muscles or difficulty speech.
- Electrical shock like sensation that moves down the back and into legs following bending of the neck.
- Headache, confusion, seizures and visual loss (signs of Reversible Posterior Leukoencephalopathy Syndrome).
- Abnormal vision, inflammation of optic nerve, partial vision loss.
- Deafness or ear toxicity causing trouble hearing or ringing in the ear.
- Lung disease may cause progressive lung stiffness, eventually affecting your ability to breathe and get enough oxygen into your bloodstream or scarring of the lung.
- Shortness of breath or breathlessness.
- Less urine than is normal for you, painful or difficult urination.
- Abnormal blood tests, which show worsening in the way the kidney is working or blood in urine.
- Kidney inflammation and kidney failure.
- Inflammation of the pancreas.
- Fast or uneven heartbeats (palpitations).
- Muscle pain and swelling, in combination with weakness, fever, or red-brown urine (symptoms of muscle damage called rhabdomyolysis), which may be fatal.

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:

- Infections.
- Runny or blocked nose, sneezing, facial pressure or pain.

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- Upper respiratory tract infection.
- Tiredness and dizziness (due to low red blood cell count, anaemia).
- Low white blood cell count (characterised by frequent infections such as fever, severe chills, sore throat or mouth ulcers).
- Loss of appetite.
- High sugar (glucose) levels in the blood.
- High potassium levels in the blood.
- High level of sodium in the blood.
- Low levels of calcium in the blood.
- Depression.
- Trouble sleeping (insomnia).
- Headache.
- Discharge with itching of the eyes and crusty eyelids.
- Nose bleeds.
- Hiccups.
- Cough.
- Nausea and vomiting.
- Inflammation of the lining of the mouth (stomatitis).
- Stomach pain.
- Constipation.
- Indigestion.
- Heartburn associated with gastric reflux.
- Skin and nail disorders.
- Dry skin on hands and feet.
- Increased sweating.

- Unusual tiredness or weakness (asthenia).
- Pain and inflammation leading to tissue damage.
- Weight gain.
- Weight loss.
- Sensation of pain or discomfort close to or at the injection site during the infusion.
- Abnormal liver function tests.

Less frequent side effects that may occur:

- Inflammation of the colon (symptoms include stomach pain and usually with blood and mucus in stools).
- Diarrhoea.
- Inflammation of the pancreas.
- Back pain.
- Painful joints and bone pain (arthralgia and skeletal pain).

Side effects with frequency unknown:

- Autoimmune reaction leading to reduction of all blood cell lines (autoimmune, pancytopenia), reduction of all blood cell lines (pancytopenia).
- Allergic vasculitis (inflammation of blood vessels).
- Oesophageal inflammation (inflammation of the lining of the oesophagus - the tube that connects your mouth with your stomach - resulting in pain and swallowing difficulty).

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ELOPLAT.

Suspected side-effects can also be reported directly to the Holder of Certificate of Registration (HCR) via the website: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. HOW TO STORE ELOPLAT

- Store at or below 30 ºC.
- Protect from light.
- Keep vial in outer carton until ready for use.
- For single use only.
- Any unused solution should be discarded.
- Chemical and physical in-use stability of Oxaliplatin 5 mg/mL concentrate for solution for infusion solutions at concentrations of 0,2 mg/mL and 1,0 mg/mL has been demonstrated for 96 hours at 2 to 8 °C when protected from light and for 24 hours at room temperature (20 °C to 25 °C), protected from light. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at room temperature (20 °C to 25 °C), unless dilution has taken place in controlled and validated aseptic conditions.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ELOPLAT contains:

The active substance of ELOPLAT is oxaliplatin.

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Eloplat 50: Each vial contains 50,0 mg oxaliplatin per 10 mL.

Eloplat 100: Each vial contains 100,0 mg oxaliplatin per 20 mL.

Eloplat 150: Each vial contains 150,0 mg oxaliplatin per 30 mL.

Eloplat 200: Each vial contains 200,0 mg oxaliplatin per 40 mL.

The other ingredients are:

Water for injection.

What ELOPLAT looks like and contents of the pack

ELOPLAT is a concentrate for solution for infusion, and is a clear, colourless to light yellow solution, practically free from particles.

ELOPLAT concentrate for solution for infusion: 50 mg/10 mL, 100 mg/20 ml, 150 mg/30 mL and 200 mg/40 mL is packed in 10 mL, 20 mL and 50 mL type I, colourless glass vials respectively, stoppered with a rubber stopper and sealed with an aluminium crimp cap.
The vials may be packed additionally in a plastic clear protective covering around the primary pack.
The vials are packed into an outer cardboard carton.
The pack sizes for ELOPLAT 50 is 1’s or 5’s or 10’s and the other strengths are packed as 1’s.
Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

2090

Patient Information Leaflet

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