

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: OXALIPLATIN PCH 50 OXALIPLATIN PCH 100
Registration Nos.: 43/26/0102-3	Dosage form & strength: Concentrate for solution for infusion. Each vial contains 50 mg or 100 mg (5 mg/ml) oxaliplatin

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: **S4**

OXALIPLATIN PCH 50 (Concentrate for solution for infusion)

OXALIPLATIN PCH 100 (Concentrate for solution for infusion)

Contains sugar (lactose monohydrate 45 mg/ml)

Read all of this leaflet carefully before you are given OXALIPLATIN PCH

- 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.
- OXALIPLATIN PCH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT OXALIPLATIN PCH IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE OXALIPLATIN PCH

3. HOW TO USE OXALIPLATIN PCH

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE OXALIPLATIN PCH

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT OXALIPLATIN PCH IS AND WHAT IT IS USED FOR:

Oxaliplatin belongs to the group of medicines called antineoplastics, which interferes with the growth of cancer cells to eventually destroy the cancer cells.

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OXALIPLATIN PCH is used to treat cancer of the rectum and colon.

OXALIPLATIN PCH is given along with other medicines to treat cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE OXALIPLATIN PCH:

OXALIPLATIN PCH should not be administered to you:

- if you are hypersensitive (allergic) to oxaliplatin or any of the other ingredients of OXALIPLATIN PCH (listed in **section 6**).
- if you are pregnant or breastfeeding your baby (see section **Pregnancy, breastfeeding and fertility**).
- if your kidney function is severely weakened or you have a kidney disease.
- if you have a condition where the bone marrow does not make enough blood cells, or none at all.
- if you already have tingling and numbness in the fingers and/or toes, and have difficulty performing delicate tasks, such as buttoning clothes.
- damage to the lungs.

Even if you are male, please ensure that you read the section of this leaflet that concerns pregnancy and breastfeeding.

Warnings and precautions:

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

- if you have had a reaction to any other platinum-containing medicine. Allergic reactions can occur during any cycle.
- if you have a kidney disease or kidney problems. You may need additional monitoring and a different dose.
- 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.

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- if you have any liver 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 PCH or delay or stop your treatment with OXALIPLATIN PCH:

- 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 PCH 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 PCH 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 PCH 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 PCH 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.

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- 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.
- 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 PCH 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).

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- 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.
- 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 PCH is working properly and to check for unwanted effects. Some of the side effects of OXALIPLATIN PCH do not have any symptoms and must be found with a blood test.
- OXALIPLATIN PCH should only be used in specialised cancer departments and under the supervision of a doctor that specialises in cancer treatment.
- OXALIPLATIN PCH 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.

Children:

OXALIPLATIN PCH is for use in adults only.

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Other medicines and OXALIPLATIN PCH:

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

Please consult your doctor, pharmacist or other healthcare provider for advice if you are using any of the following medicines:

- Anticoagulants (medicines like warfarin or heparin that prevent your blood from forming clots)
- Medicines that reduce the production of a number of blood cells (red blood cells, white blood cells and platelets)
- Tell your doctor that you are using OXALIPLATIN PCH if you are going to be vaccinated. OXALIPLATIN PCH may lower your body's resistance and there is a chance you might get the infection the vaccine is meant to prevent.

Additional testing may be required if you use other medicines that is known to:

- Prolong the QT interval (abnormal electrical signal of the heart), such as quinidine, disopyramide, amiodarone, sotalol, dofetilide and ibutilide
- Be associated with rhabdomyolysis (muscle damage) such as statins, antipsychotics, zidovudine, colchicine, selective serotonin reuptake inhibitors and lithium (see **section 2, Warnings and precautions**).

Not all the medicines that would interact with OXALIPLATIN PCH are listed above, please tell your doctor or healthcare provider about any other medicine that you are using, prior to using OXALIPLATIN PCH.

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OXALIPLATIN PCH with food and drink:

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

OXALIPLATIN PCH should not be used if you are pregnant or breastfeeding your baby. Tell your doctor right away if you think you have become pregnant while receiving OXALIPLATIN PCH.

Effective birth control to prevent pregnancy is advised during OXALIPLATIN PCH treatment and after the end of OXALIPLATIN PCH treatment for the following 9 months for women and for 6 months for men.

OXALIPLATIN PCH may have an anti-fertility effect which could be irreversible.

Men treated with OXALIPLATIN PCH are therefore advised not to father a child during and up to 6 months after OXALIPLATIN PCH treatment and to seek advice on conservation of sperm prior to OXALIPLATIN PCH treatment.

Driving and using machines:

OXALIPLATIN PCH may cause some people to become nauseous and to have headaches, feel dizzy and can affect your vision and sense of balance.

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It is not always possible to predict to what extent OXALIPLATIN PCH may interfere with your daily activities. You should ensure that you do not engage in driving or operate any machinery until you are aware of the measure to which OXALIPLATIN PCH affects you.

3. HOW TO USE OXALIPLATIN PCH:

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

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

OXALIPLATIN PCH may only be given to adults.

For single use only.

The dose of OXALIPLATIN PCH is based on your body surface area (calculated from your height and weight).

The dose will also depend on results of blood tests and whether you have previously experienced side effects with OXALIPLATIN PCH.

The recommended dose for adults including the elderly is 85 mg/m² of body surface.

Method and route of administration:

- OXALIPLATIN PCH 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 OXALIPLATIN PCH.
- OXALIPLATIN PCH is given by slow injection into one of your veins (an intravenous infusion) over a 2 to 6-hour period.

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- OXALIPLATIN PCH will be given to you at the same time as folinic acid and before the infusion of 5-fluorouracil.
- The needle must remain in the vein while the drug is being given. If the needle comes out or becomes loose, or the solution is going into the tissue outside the vein (you may feel discomfort or pain) – tell the nurse or doctor immediately.

Frequency of administration:

You should usually receive your infusion once every two weeks.

Duration of treatment:

The duration of the treatment will be determined by your doctor

Your treatment will last a maximum of 6 months when used after complete resection of your tumour.

If OXALIPLATIN PCH solution comes into contact with your skin, wash immediately and thoroughly with soap and water.

If you receive more OXALIPLATIN PCH than you should:

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

If you forget to use OXALIPLATIN PCH:

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

4. POSSIBLE SIDE EFFECTS:

OXALIPLATIN PCH can have side effects.

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

Be sure that you discussed with your doctor the possible side effects of OXALIPLATIN PCH.

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

Frequent side effects:

- allergies/allergic reactions, occurring mainly during infusion, sometimes fatal
- stomatitis / mucositis (sore lips or mouth ulcers)
- low platelet count, abnormal bruising (thrombocytopenia). Your doctor will take blood to check that you have sufficient blood cells before you start treatment and before each subsequent course
- 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 $> 38.3^{\circ}\text{C}$ or a prolonged fever $> 38^{\circ}\text{C}$ for more than one hour (febrile neutropenia)
- 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
- pain in the chest or upper back, difficulty breathing and coughing up blood (symptoms of clots in the lungs).

Less frequent side effects:

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- serious infection of the blood (sepsis), which may be fatal
- blockage or swelling of the bowel
- reversible short-term loss of vision
- difficulty in hearing, vertigo, ringing in ears
- 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 bruising, bleeding or signs of infection such as a sore throat and high temperature
- persistent or severe diarrhoea or vomiting
- headache, altered mental functioning, seizures (fits) and abnormal vision from blurriness to vision loss (symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder)
- extreme tiredness with decreased number of red blood cells, and shortness of breath (haemolytic anaemia), alone or combined with low platelet count, abnormal bruising (thrombocytopenia)
- scarring and thickening in the lungs with difficulties in breathing, sometimes fatal (interstitial lung disease)
- pain in upper abdomen and pain associated with nausea and vomiting
- kidney disease where you pass little or no urine (symptoms of acute renal failure)
- vascular disorders of the liver (symptoms include abdominal pain and swelling, weight gain and tissue swelling of the feet, ankles or other parts of the body).

Side effects with unknown frequency:

- 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)
- auto-immune reaction leading to reduction of all blood cell lines (autoimmune pancytopenia) (symptoms include easy bleeding, easy bruising, shortness of breath, extreme lethargy and weakness, and an increased risk of infection due to the immune compromised state)

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- 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
- spasm of the throat causing difficulty in breathing
- 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.

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:

- OXALIPLATIN PCH causes temporary 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.
- OXALIPLATIN PCH can affect the nerves (peripheral 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.

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○ 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. Although in the majority of cases these symptoms disappear 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.

- OXALIPLATIN PCH 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. 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.
- sneezing
- weight changes, loss or lack of appetite, taste disorders, constipation
- decreased levels of calcium in the blood
- depression and insomnia (difficulty sleeping)
- conjunctivitis and visual problems
- chest pain
- high blood pressure
- lung disorders and runny nose
- OXALIPLATIN PCH may cause diarrhoea, mild nausea (feeling sick) and vomiting (being sick); however medication to prevent the sickness is usually given before treatment and may be continued after treatment.
- headache, back pain
- swelling of the nerves to the muscles, neck stiffness
- abnormal bleeding including nose bleeds
- stomach pain

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- indigestion and heart burn, hiccups, flushing and dizziness
- increased sweating and nail disorders, flaking skin
- allergic reactions, skin rash including red and itchy skin, mild hair loss (alopecia)
- joint pain and bone pain
- pain on passing urine and changes in kidney function, changes of frequency of urination, dehydration
- blood in the urine/stools, swelling of the veins
- sensation of discomfort close to or at the injection site during the infusion
- fever, rigors (tremors), mild or severe tiredness, body pain
- alteration in blood tests including those relating to abnormalities on liver function
- falls.

Less frequent side effects:

- nervousness
- abnormal tongue sensation possibly altering speech
- loss of hearing.

Side effects with unknown frequency:

- a benign tumour, or lesion, that forms in the liver (feel a lump or pain in the stomach)
- allergic vasculitis (inflammation of blood vessels)
- convulsion (uncontrolled shaking of the body)
- myocardial infarction (heart attack), angina pectoris (pain or uncomfortable feeling in the chest)
- oesophageal inflammation (inflammation of the lining of the oesophagus - the tube that connects your mouth with your stomach- resulting in pain and swallowing difficulty)
- risk of new cancers. Leukaemia, a form of blood cancer, has been reported in patients after taking oxaliplatin concentrate for solution for infusion in combination with certain other medicines. Talk to your

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doctor about the potential for increased risk of this type of cancer when you are given OXALIPLATIN PCH 5 mg/ml concentrate for solution for infusion and certain other medicines.

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 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 OXALIPLATIN PCH.

5. HOW TO STORE OXALIPLATIN PCH:

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Do not freeze the vial or solution for infusion.

Infusion preparation:

From a microbiological point of view the solution for infusion should be used immediately after preparation. If not used immediately, it should be stored at 2 °C to 8 °C for not longer than 24 hours.

Do not use OXALIPLATIN PCH after the expiry date printed on the carton or vial.

Return all unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

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What OXALIPLATIN PCH contains:

The active substance is oxaliplatin.

Each OXALIPLATIN PCH 50 vial contains 50 mg oxaliplatin.

Each OXALIPLATIN PCH 100 vial contains 100 mg oxaliplatin.

The other ingredients are lactose monohydrate and water for injection.

What OXALIPLATIN PCH looks like and contents of the pack:

OXALIPLATIN PCH is a clear and colourless to almost colourless solution that is free from visible particles.

OXALIPLATIN PCH 50 is filled in a clear, colourless Type I glass vial (10R) with dark grey bromobutyl rubber stopper and aluminium seal with a coloured polypropylene cover.

OXALIPLATIN PCH 100 is filled in a clear, colourless Type I glass vial (20R) with dark grey bromobutyl rubber stopper and aluminium seal with a coloured polypropylene cover.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

2090

Tel: 011 055 0200

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