

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZALITIN 50

ZALITIN 100

Oxaliplatin, concentrate for solution for infusion.

Sugar free

Read all of this leaflet carefully before you start taking ZALITIN.

- 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 **ZALITIN** is and what it is used for
2. What you need to know before you take **ZALITIN**
3. How to take **ZALITIN**
4. Possible side effects
- 5 How to store **ZALITIN**.
6. Contents of the pack and other information

1. What **ZALITIN** is and what is it used for:

The active substance of **ZALITIN** is oxaliplatin.



ZALITIN is an antineoplastic or anticancer medicine that contains oxaliplatin, which is a medicine which has platinum in its chemical structure. It is used to treat cancer of the large bowel (colon and rectum).

ZALITIN is used in combination with other anticancer medicines called 5-fluorouracil (5-FU) and folinic acid.

2. What you need to know before you take ZALITIN:

ZALITIN should not be administered to you:

- If you have known allergies to **ZALITIN** or to any other ingredients (listed in section 6).
- If you are breastfeeding.
- If you already have a reduced number of red or white 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 (peripheral nerve damage).
- If you have severe kidney problems.

Warnings and precautions

Tell your doctor or healthcare professional before being given **ZALITIN**:

- If you are planning a pregnancy. It is very important that you discuss this with your doctor before you receive any treatment (see Pregnancy, breastfeeding and fertility). **ZALITIN** may have an anti-fertility effect, which could be irreversible. It is not recommended that you become pregnant during treatment with **ZALITIN**, and a barrier method of contraception (condoms) should be used. If a pregnancy occurs despite the use of contraception,



please inform your doctor immediately. Barrier contraceptive measures

(condoms) must be used during and after cessation of therapy (4 months for women and 6 months for men).

- 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 any liver problems.
- 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.

Tell your doctor or health care professional immediately if any of the following applies to you at any time (see section 4). Your doctor may need to treat you for these events. Alternatively, your doctor may need to reduce the dose of **ZALITIN** or delay or stop your treatment with **ZALITIN**:

- 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 **ZALITIN** 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 health care professional must stop treatment immediately and initiate treatment of local symptoms (see section 3).



- If you have an unpleasant sensation in the throat, in particular when swallowing, and have a sensation of shortness of breath, during or after the treatment. Your next infusion should be administered over a longer period. Avoidance of exposure to cold and ingestion of cold food or beverages during or within hours following the infusion may reduce symptoms.
- 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 have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss. 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 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 experience sore lips or mouth ulcers. Your doctor might decide to delay your next treatment depending on your blood results.
- If you have signs of infection such as a sore throat and high temperature (a single temperature of $> 38,3^{\circ}\text{C}$ or a sustained temperature of $> 38^{\circ}\text{C}$ 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. **ZALITIN** can also cause a reduction of the number of blood cells, your doctor will check your blood frequently.
- If you experience unexplained respiratory symptoms such as a non-productive cough, difficulty in breathing or crackles.
- 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 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 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 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.

Other medicines and ZALITIN

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

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).

Pregnancy, breastfeeding and fertility

Pregnancy:

If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor before you receive any treatment.

It is not recommended that you become pregnant during treatment with **ZALITIN**, and a barrier method of contraception (condoms) should be used. If a pregnancy occurs despite the use of contraception, please inform your doctor immediately. Barrier contraceptive measures (condoms) must be used during and after cessation of therapy (4 months for women and 6 months for men).

Breastfeeding

You must not breastfeed while you are being treated with **ZALITIN**.

Fertility

ZALITIN may have an anti-fertility effect which could be irreversible, and patients are advised to seek advice on conservation of sperm prior to treatment (see section 2, Warnings and precautions).

Driving and using machines



ZALITIN treatment may cause dizziness, nausea and vomiting, and other neurological symptoms that affect gait and balance and may influence the ability to drive and use machines. Vision disturbances may affect your ability to drive and use machines.

3. How to take **ZALITIN**:

ZALITIN will be prescribed for you by a specialist in cancer treatment. You will not be expected to give yourself **ZALITIN**. It will be given to you by a person qualified to do so.

ZALITIN is given by infusion into a vein (this is called an intravenous infusion) over a 2- to 6-hour period.

ZALITIN must be diluted before it can be injected. The injection is made by mixing the concentrated injection solution with 5 % glucose solution. About 250 mL to 500 mL of the glucose solution is usually used.

The **ZALITIN** injection will be made up in a special area before the doctor or nurse administers it to you.

The dose of **ZALITIN** is calculated according to your body surface area. This the doctor calculates from your height and weight. The usual dose for adults is 85 mg/m² of body surface area once every 2 weeks. Your doctor may change the dose in some instances.

Each course of treatment is called a cycle; your doctor will tell you how many cycles you will receive.

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



To prevent the onset of nausea and vomiting, your doctor may prescribe an additional treatment.

While you are being given **ZALITIN** and between each treatment cycle (see section 2):

Things you must do:

- The needle must remain in the vein while the medicine 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 doctor or nurse immediately.
- Avoid cold foods and drinks and cover skin prior to exposure to cold during or within 48 hours following being given **ZALITIN**, since neurological effects may be brought on or worsened by exposure to cold.
- Contact your doctor immediately if you develop fever, particularly in association with persistent diarrhoea or evidence of infection since this may indicate low blood count.
- Contact your doctor if persistent vomiting, diarrhoea, signs of dehydration, cough or breathing difficulties or signs of allergic reaction occur.
- Visual disturbance is a rare side effect of **ZALITIN**. Contact your doctor if this happens to you, and do not drive and use machinery until your vision is clear.

If you receive more ZALITIN than you should

Your doctor will decide what dose of **ZALITIN** you need, and this will be given under close supervision, usually in a hospital setting. The risk of an overdose



in these circumstances is low. In the event of an overdose occurring, your doctor will decide on the treatment necessary.

If you missed a dose of ZALITIN

Your doctor will make sure you receive **ZALITIN** at the right time. Contact your doctor if you are unsure about the timing of your next cycle.

4. Possible side effects

ZALITIN can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor or nurse as soon as possible if you do not feel well while **ZALITIN** is being given to you. You should also tell your doctor if you do not feel well between courses of **ZALITIN**.

It is important to understand the side effects that **ZALITIN** may cause, even though you may not experience them. As well as the predictable side effects of **ZALITIN**, there are other effects that occur.

If you have any side effects or notice anything unusual, it is important to inform your doctor before your next treatment. Your doctor will decide whether such effects are because of your treatment, and what action needs to be taken.

If any of the following happens, stop using ZALITIN 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, difficulty in swallowing, swelling of the face, lips, mouth, tongue, throat 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.

These are all serious side effects. If you have them, you may have had a serious reaction to **ZALITIN**. You might 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 (see section 2):

- Abnormal bruising, bleeding or signs of infection such as sore throat and high temperature.
- Persistent or severe diarrhoea or vomiting.
- Presence of blood or dark-brown coffee-coloured granules in your vomit or dark-coloured/tarry stools.
- Sore lips or mouth ulcers (mucositis).
- Unexplained respiratory symptoms such as dry cough, difficulties in breathing or crackles.
- 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).
- 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).

- 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) and kidney disease where you pass little or no urine (symptoms of haemolytic-uraemic syndrome).
- Sensation of discomfort close to or at the injection site during the infusion.
- 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 or hospitalisation.

Tell your doctor before your next treatment if you experience the following side effects:

- Physical condition: Before each treatment with **ZALITIN** you will be examined for any condition that may be affected by chemotherapy (e.g. infection, loss of feeling). This will include those conditions caused by previous treatment, those caused by your disease, and those caused by other factors.
- Loss of feeling: **ZALITIN** can affect nerves in the hands and feet. This is common soon after treatment and can appear as tingling or numbness in the fingers and toes and may be made worse by cold temperatures or by contact with cold water or other cold objects. These symptoms often go away



between treatments but may last longer and get worse with repeated

treatment. In some patients the limbs may become weak or painful. However, in most patients these symptoms improve after treatment is stopped. Tell your doctor if any of these effects occur.

- Nausea and vomiting: Severe nausea and vomiting is uncommon with **ZALITIN**. Mild nausea and vomiting are more common. Medication to prevent the nausea and vomiting caused by **ZALITIN** will be given before treatment and may sometimes be continued after treatment.
- Low blood counts: **ZALITIN** frequently affect the body's ability to make blood cells. Three types of blood cells are checked before each treatment: platelets which help to control bleeding; white blood cells which help fight infection and red blood cells which move oxygen around the body. If your blood count is too low, your treatment may be postponed, or the dose reduced. Tell your doctor if you notice any bruising or abnormal bleeding or have an infection. These may be signs of low blood count.
- Difficulty swallowing: Some patients may experience a sudden, temporary feeling of difficulty with swallowing or breathing. This sensation, if it occurs, usually happens during the infusion or within hours after the infusion. It may be triggered by swallowing a cold drink. Although unpleasant, this feeling does not last long and goes away by itself. Tell your doctor if this happens to you.

Tell your doctor if you notice any of the following:

Frequent side effects:



- headache, back pain
- swelling of the nerves to your muscles, neck stiffness, abnormal tongue sensation possibly altering speech
- abdominal pain
- constipation
- hiccups
- loss or lack of appetite
- weight changes
- indigestion and heartburn
- flushing
- dizziness
- coughing, difficulty in breathing
- infection due to a reduction in white blood cells
- changes in blood tests including those relating to abnormalities in liver function
- hair loss (alopecia)
- fever, tiredness
- inflammation around the injection site
- skin rash, allergic reactions
- discharge with itching of the eyes and crusty lids (conjunctivitis)
- altered taste, abnormal tongue sensation
- abnormal bleeding including nose bleeds and blood in the urine
- blood clots and high blood pressure
- chest pain or feeling of chest pressure



Applicant/PHCR: Innovata Pharmaceuticals Pty Ltd

Product Proprietary Name: ZALITIN 50 mg/10 ml and ZALITIN 100 mg/20 ml

Dosage Form & Strength: Concentrate for infusion, 50 mg/10 ml and 100 mg/20 ml

- increased sweating, nail disorders, flaking skin (hand and foot syndrome)
- lung disorders and runny nose
- joint pain and bone pain
- depression and insomnia
- pain on passing urine, changes of frequency of urination
dehydration
- decreased levels of calcium in the blood
- increased blood glucose
- blockage or swelling of the bowel
- falling, which may lead to injuries.

Less frequent side effects:

- serious infection of the blood (sepsis), which may be fatal
- nervousness
- visual disturbance, transient visual loss, reversible following therapy
discontinuation
- scarring and thickening in the lungs with difficulties in breathing, sometimes
fatal (interstitial lung disease)
- loss of hearing
- voice disturbance
- vascular disorders of the liver.

~~Side effects with frequency unknown:~~

- allergic vasculitis (inflammation of blood vessels)



- autoimmune reaction leading to reduction of all blood cell lines (autoimmune
- pancytopenia), reduction of all blood cell lines (pancytopenia)
- serious infection of the blood and low blood pressure (septic shock), which may be fatal
- convulsion (uncontrolled shaking of the body)
- spasm of the throat causing difficulty in breathing
- 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
- abnormal heart rhythm (QT prolongation), that can be seen on electrocardiogram (ECG), which may be fatal
- myocardial infarction (heart attack), 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)
- 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
- risk of new cancers. Leukaemia, a form of blood cancer, has been reported in patients after taking **ZALITIN** in combination with certain other medicines.



Talk to your doctor about the potential for increased risk of this type of cancer when taking **ZALITIN** and certain other medicines.

If you notice any side effects not listed 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 **ZALITIN**.

5. How to store ZALITIN

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

Store at room temperature at or below 25 °C.

Do not freeze.

Protect from light (keep in outer carton until use)

Infusion preparation: If not used immediately, should be stored at $\leq 25^{\circ}\text{C}$ for 12 hours and at 2°C to 8°C for not longer than 24 hours.

Inspect visually prior to use. Only clear solutions without particles should be used.

The medicinal product is for single use only. Any unused solution should be discarded.

Do not use this medicine after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

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



6. Contents of the pack and other information

What ZALITIN contains:

The active substance is: Oxaliplatin 50 mg/10 mL and 100 mg/20 mL.

The other ingredient is: Water for injections

What ZALITIN looks like and contents of the pack

Concentrate for solution for infusion: A clear, colourless solution.

ZALITIN 50 mg/10 mL and **ZALITIN** 100 mg/20 mL concentrate for infusion is packed in a 20H, Colourless, borosilicate, type I glass vial with a 20mm, Teflon-coated chlorobutyl rubber stopper and a 20mm, aluminium seal with a plastic flip-off cap, packed in an outer carton with a package insert.

Holder of Certificate of Registration

Innovata Pharmaceuticals Pty Ltd

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Applicant/PHCR: *Innovata Pharmaceuticals Pty Ltd*

Product Proprietary Name: *ZALITIN 50 mg/10 ml and ZALITIN 100 mg/20 ml*

Dosage Form & Strength: *Concentrate for infusion, 50 mg/10 ml and 100 mg/20 ml*

Access to the corresponding Professional information is contained in the
packaging or

Follow the link for the corresponding Professional Information for **ZALITIN**:

pi-pil-repository.innovata.co.za, alternatively, please scan the QR code below:

**PLACE
HOLDER:**

**The QR code to
be included after
approval.**

