

Oxaliplatin SUN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Oxaliplatin SUN?

Oxaliplatin SUN contains the active ingredient oxaliplatin. Oxaliplatin SUN is used to treat cancer of the large intestine and rectum (colorectal cancer).

For more information, see Section 1. Why am I using Oxaliplatin SUN in the full CMI.

2. What should I know before I use Oxaliplatin SUN?

Do not use if you have ever had an allergic reaction to Oxaliplatin SUN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Oxaliplatin SUN in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxaliplatin SUN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Oxaliplatin SUN?

- Oxaliplatin SUN will be given to you as an infusion into one of your veins (this is called an intravenous infusion). The infusion will be given over 2-6 hours.
- The usual dose is 85mg/m² every two weeks. Your doctor may change the dose in some circumstances.
- Each course of treatment is called a cycle; your doctor will tell you how many cycles you will receive.

More instructions can be found in Section [4. How do I use \[medicine name\]?](#) in the full CMI.

5. What should I know while using Oxaliplatin SUN?

Things you should do	<ul style="list-style-type: none">• You must tell your doctor if:<ul style="list-style-type: none">□ you have had a reaction to any other platinum compound□ you have severe kidney disease, nerve damage (neuropathy) or any other medical condition□ you are taking any other medicines, including medicines that you have bought without a prescription from a pharmacy, supermarket or health food shop.
Driving or using machines	<ul style="list-style-type: none">• Visual disturbance is a rare side effect of Oxaliplatin SUN. Contact your doctor if this happens to you, and do not drive or use machinery until your vision is clear.
Looking after your medicine	<ul style="list-style-type: none">• Store in a cool dry place where the temperature does not exceed 25 degrees Celsius. Protect from light. Do not freeze.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Before each treatment with Oxaliplatin SUN you will be examined for any condition that may be affected by chemotherapy (for example, infection, or loss of feeling). Common side effects include loss of feeling, nausea, vomiting, diarrhea, low blood counts and difficulty swallowing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Oxaliplatin SUN

Active ingredient(s): *oxaliplatin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxaliplatin SUN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Oxaliplatin SUN.**

Where to find information in this leaflet:

- [1. Why am I using Oxaliplatin SUN?](#)
- [2. What should I know before I use Oxaliplatin SUN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Oxaliplatin SUN?](#)
- [5. What should I know while using Oxaliplatin SUN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Oxaliplatin SUN?

Oxaliplatin SUN contains the active ingredient oxaliplatin.

Oxaliplatin SUN is an antineoplastic drug. Oxaliplatin works by interfering with cancer cell growth. Because of the similarities between cancer cells and normal cells, anticancer drugs often have unwanted effects on the body.

Oxaliplatin SUN is used to treat cancer of the large intestine and rectum (colorectal cancer). Oxaliplatin SUN is used with two other anti-cancer drugs, fluorouracil (FU), and folinic acid.

Your doctors have decided to treat you with Oxaliplatin SUN because they believe that the benefit of Oxaliplatin SUN treatment will be greater than the unwanted effects.

Many of the side effects from anticancer drugs are predictable and can be prevented or lessened. Your doctor and other staff will take all of the precautions needed to reduce the unwanted effects of treatment.

Oxaliplatin SUN is only available on a prescription from your doctor.

2. What should I know before I use Oxaliplatin SUN?

Warnings

Do not use Oxaliplatin if:

- you are allergic to oxaliplatin, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- You must not receive Oxaliplatin SUN if you are pregnant or breastfeeding.
- You must not be given Oxaliplatin SUN if you have a blood disorder with a reduced number of platelets or white blood cells.
- You must not be given Oxaliplatin SUN if you have nerve damage such as numbness or weakness of the arms or legs (neuropathy).
- You must not receive Oxaliplatin SUN if you have severe kidney disease.

Check with your doctor if you:

- have had a reaction to any other platinum compound
- have severe kidney disease you have nerve damage (neuropathy)
- have any other medical condition that he or she is not aware of
- take any medicines for any other condition, including medicines that you have bought without a prescription from a pharmacy, supermarket or health food shop

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not receive Oxaliplatin SUN if you are pregnant or breastfeeding.

Oxaliplatin may cause birth defects if you are being treated with it at the time of conception or it is given to women who are already pregnant. Adequate contraception is required during treatment with oxaliplatin. You should discuss this with your doctor. Nursing mothers are advised not to breastfeed while receiving oxaliplatin, as the effect of breast milk from such patients is unknown.

Paediatric Use

- Oxaliplatin SUN is not recommended in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Oxaliplatin SUN.

4. How do I use Oxaliplatin SUN?

How much to take / use

- Oxaliplatin SUN will be given to you as an infusion into one of your veins (this is called an intravenous infusion). The infusion will be given over 2-6 hours.
- The dose of Oxaliplatin SUN is calculated according to your body surface area, which is calculated from your weight and height.
- The usual dose is 85mg/m² every two weeks. Your doctor may change the dose in some circumstances.
- Each course of treatment is called a cycle; your doctor will tell you how many cycles you will receive.
- Oxaliplatin SUN will be used with fluorouracil (FU) and folinic acid.

If you use too much Oxaliplatin SUN

Your doctor will decide what dose of Oxaliplatin SUN 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.

5. What should I know while using Oxaliplatin SUN?

Things you should do

Avoid cold foods and drinks and cover skin prior to exposure to cold during or within 48 hours following being given oxaliplatin, 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 Oxaliplatin SUN. Contact your doctor if this happens to you, and do not drive or use machinery until your vision is clear.

Driving or using machines

Visual disturbance is a rare side effect of Oxaliplatin SUN. Contact your doctor if this happens to you, and do not drive or use machinery until your vision is clear.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

If you need to store Oxaliplatin SUN before you take it with you to hospital, store it in a cool dry place where the temperature does not exceed 25 degrees Celsius. Protect from light. Do not freeze.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

If you have any side effects or notice anything unusual it is important to inform your doctor before your next treatment.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Your doctor will decide whether such effects are because of your treatment, and what action needs to be taken.

This section explains the side effects of Oxaliplatin SUN, and some of the checks made before each treatment to prevent excessive side effects.

- ❖ **Physical Condition.** Before each treatment with Oxaliplatin SUN you will be examined for any condition that may be affected by chemotherapy (for example, infection, or loss of feeling). This will include those conditions caused by previous treatment, those caused by your disease, and those caused by other things.
- ❖ **Loss of feeling.** Oxaliplatin SUN can affect nerves in the hands and feet. This is common soon after treatment and can appear as tingling or numbness in the fingers or 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 things happen. Your doctor will examine you before treatment to see if you are affected.

- ❖ Nausea and Vomiting. Severe nausea and vomiting is uncommon with Oxaliplatin SUN. Mild nausea and vomiting is more common. Medication to prevent the sickness caused by Oxaliplatin SUN will be given before treatment, and may sometimes be continued after treatment.

- ❖ Diarrhoea. Severe diarrhoea may occur during treatment with Oxaliplatin SUN.

If you suffer from persistent or severe diarrhoea or vomiting, contact your doctor urgently for treatment advice.

- ❖ Low Blood Counts. Oxaliplatin SUN can affect the body's ability to make blood cells. There are three types of blood cells checked before each treatment; platelets, which help 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 a 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, nurse or pharmacist if you notice any of the following and they worry you:

- abdominal pain
- constipation
- anorexia
- mild hair loss (alopecia)
- inflammation around the injection site
- tiredness or unusual weakness
- conjunctivitis
- runny or blocked nose
- altered taste
- nose bleeds
- voice disturbance (rare)
- loss of hearing (rare)
- light headedness or dizziness
- cough
- hiccups
- jaw spasm

- high blood pressure
- back pain
- joint pain

Tell your doctor, nurse or pharmacist as soon as possible if you notice any of the following:

- sore lips or mouth
- mouth ulcers
- fever
- skin rash or hives
- abnormal tongue sensation
- lung disorders (rare)
- visual disturbance (rare)
- infection in the body (symptoms include lightheadness, tiredness, fever, feeling unwell)
- abnormal clotting followed by abnormal bleeding
- duodenal stomach ulcer, which may cause abdominal pain
- headaches or confusion, particularly if associated with visual disturbances.

Tell your doctor, nurse or pharmacist immediately, and go to your nearest Accident and Emergency centre if you notice any of the following:

- allergic reactions
- swelling of the face, lips, mouth, touch or throat
- chest pain or feeling of chest pressure
- coughing
- a wheezing or whistling sound when inhaling
- abnormal changes to your heart rate
- difficulty breathing
- feeling light-headed or dizzy
- breakdown of muscle tissue causing muscle fibres to be released into the blood. Symptoms include dark, red urine, decreased urine output, muscle stiffness or aching
- shortness of breath and looking pale
- serious lung infections. Symptoms include fever, chills, shortness of breath, and a cough which produces yellow-green phlegm and occasionally blood
- convulsions, fits or seizures
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhea

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Some of these side effects (for example, changes in liver or kidney function, changes in blood pressure, changes in blood glucose or calcium levels) can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Oxaliplatin SUN contains

Active ingredient (main ingredient)	Oxaliplatin 50mg, 100mg or 200mg
Other ingredients (inactive ingredients)	lactose monohydrate and water for injections.
Potential allergens	lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Oxaliplatin SUN looks like

Oxaliplatin SUN comes as a concentrated solution in a glass vial.

A box contains 1 vial.

Oxaliplatin SUN 50mg/10mL concentrated solution for injection AUSTR 173346

Oxaliplatin SUN 100mg/20mL concentrated solution for injection AUSTR 173348

Oxaliplatin SUN 200mg/40mL concentrated solution for injection AUSTR 173350

Who distributes Oxaliplatin SUN

Sun Pharma ANZ Pty Ltd

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This leaflet was prepared in April 2021.