

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrOXALIPLATIN

Oxaliplatin Injection,

Read this carefully before you start taking **Oxaliplatin** and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Oxaliplatin**.

Serious Warnings and Precautions

- Oxaliplatin should be given by a healthcare professional experienced in the use of anti-cancer drugs.
- Oxaliplatin can cause serious and possible fatal side effects including:
 - **Severe allergic reactions** that may happen within minutes of receiving Oxaliplatin
 - **Severe Liver problems.** This may include issues with function, damage or death of liver cells.
 - **Myelosuppression:** This is when your blood counts are low. It can affect red blood cells (anemia), white blood cells (neutropenia), or platelets (thrombocytopenia). Myelosuppression can be severe and may increase your risk for infection or bleeding. It may be worse as the number of doses you receive increases.
 - **Serious and fatal infections** after receiving some vaccines.
 - **Neuropathy:** This is when the nerve is damaged and may result in changes to your nerves.
 - **Interstitial Lung Disease:** This is a condition that results in respiratory problems that may result in death.
 - **Arrhythmia:** This is a condition that results in irregular heartbeats
 - **Intestinal ulcers:** This is a condition in which there are open sores on the inside of the lining of the stomach.
 - **Bleeding, perforation** (a hole in the intestine wall) or a lower blood flow to the intestines
 - **Rhabdomyolysis:** A condition where your muscles breakdown and in which there are muscular adverse effects

What is Oxaliplatin used for?

Oxaliplatin is a medication used in combination with two other medications (5-fluorouracil (5-FU) and leucovorin) to treat:

- patients with colon cancer, after surgery to remove the tumor.
- patients with a kind of cancer called metastatic colorectal cancer.

How does Oxaliplatin work?

Every cell in your body contains genetic material. This genetic material provides “information” for organs, tissue growth and tissue functioning.

Oxaliplatin links to the genetic material in the cancer cell and stops the replication process of the cancer cell. This causes the death of the cancer cell.

What are the ingredients in Oxaliplatin?

Medicinal ingredients: oxaliplatin

Non-medicinal ingredients: sodium hydroxide, tartaric acid, and water for injection

Oxaliplatin comes in the following dosage forms:

Oxaliplatin solution for injection (5 mg/mL)

Available in vials containing 50 mg / 10 mL, 100 mg / 20 mL and 200 mg / 40 mL.

Do not use Oxaliplatin if:

- You are allergic to oxaliplatin or other platinum containing ingredients or to any of the ingredients in the product or any part of the container (see the section “**What are the ingredients in Oxaliplatin**”)
- You have numbness, weakness, prickling or tingling in your feet, hands, legs and/or arms
- You have a severe kidney disease.
- You are or are planning to become pregnant.
 - Use effective birth control to keep from getting pregnant. If you think you have become pregnant while using the medicine, tell your healthcare professional right away.
 - Men should not father a child while receiving Oxaliplatin and up to 6 months after.
- You are breast-feeding or plan to breastfeed.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Oxaliplatin. Talk about any health conditions or problems you may have, including if you:

- Have not taken your premedication as directed.
- Have kidney disease or are taking medication that can damage the kidney. Your healthcare professional will check on you regularly.
- Have heart disease called “QT prolongation.”
- Have recently received or plan to receive any vaccines.

Other warnings you should know about:

Pregnancy Information for Females and Males

Female Patients

- If you are able to become pregnant, use effective birth control.

- Use effective birth control during treatment with oxaliplatin and for at least 9 months after the last dose.

Do not breast-feed while taking Oxaliplatin and for 3 months after the last dose.

Male Patients

- Avoid fathering a child while you are taking Oxaliplatin.
- If you have a female partner that can become pregnant, use effective birth control.
 - Use effective birth control during treatment with oxaliplatin and for at least 6 months after the last dose.
- Talk to your healthcare professional about conserving your sperm before treatment. Oxaliplatin may have an impact on your ability to have children and this effect could be permanent.

Check-ups and Testing:

Your healthcare professional will check your blood at regular visits while you are using this medicine. Your healthcare professional will let you know if your platelets, white or red blood cells are low.

Nerve Changes (Neuropathy):

- Nerves changes (neuropathy) can occur with Oxaliplatin (see the section “**What are possible side effects from using Oxaliplatin**”).
- Being exposed to the cold is one of the most common triggers of neuropathy and may cause unpleasant sensations. To avoid these sensations:
 - Avoid cold drinks and the use of ice cubes in drinks.
 - Avoid cold temperatures and cold objects.
 - Cover your skin if you must go outside in cold temperatures. Do not put ice or ice packs on your body.
 - Do not breathe deeply when exposed to cold air.
 - Do not take things from the freezer or refrigerator without wearing gloves.
 - Do not run the air conditioner at high levels in the house or in the car in hot weather.
- A less common symptom of neuropathy is a condition called pharyngolaryngeal dysesthesia. This is the feeling of tightness or discomfort in the throat, making it seem difficult to breathe or swallow.
- Some people may experience more debilitating symptoms of neuropathy, which may interfere with daily activities such as the following:
 - Writing
 - Buttoning clothes
 - Swallowing
 - Difficulty walking
 - Picking up things

Driving and Using Machines

Oxaliplatin may cause dizziness, other conditions that affect balance, and cause vision problems (including reversible short-term loss of vision). Do not drive or operate machines until you know how you respond to Oxaliplatin.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Oxaliplatin:

- Oxaliplatin may interact with anticoagulants (medicine used to prevent blood clots).

How to take Oxaliplatin:

Usual dose:

Your healthcare professional will decide how much Oxaliplatin is right for you and how often you should receive it.

Oxaliplatin is an injectable medication that is given by intravenous infusion (injected slowly in a vein) every 2 weeks. It is given to you together with two other medicines called leucovorin and 5-fluorouracil (5-FU).

You may have to take medication before each treatment begins. This is called premedication. The purpose of this is to help lessen the nausea you may experience. Your healthcare professional will tell you exactly what premedication you need to take and for how long.

If you forget to take your premedication as directed, make sure to tell your healthcare professional before you get your Oxaliplatin treatment. Be sure to keep all appointments.

Overdose:

This medicine will be given to you in a hospital, under the supervision of a healthcare professional. It is unlikely that you will be given too much or too little, however, tell your healthcare professional if you have any concerns. Too much Oxaliplatin may affect your blood count, heart, kidneys, liver, lungs, or nerves.

Tell your healthcare professional if you have extreme fatigue, diarrhea, hair loss, heart problems, difficulty breathing, or abnormal vision.

If you think you, or a person you are caring for, have taken too much Oxaliplatin, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

This medicine needs to be given on a fixed schedule. If you miss an infusion, call your healthcare professional.

What are possible side effects from using Oxaliplatin?

These are not all the possible side effects you may have when taking Oxaliplatin. If you experience any side effects not listed here, tell your healthcare professional.

- Nausea.
- Diarrhea.
- Vomiting.
- Fatigue.
- Sores in the mouth (stomatitis).
- Change in taste.
- Pain at the injection site.
- Pain in a joint.
- Nose bleeding.
- Hiccups.
- High blood pressure.
- Constipation.
- Stomach pain.
- Loss of appetite.
- Hair loss.
- Reversible short-term loss of vision.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
Persistent vomiting or diarrhea		√	
Persistent cough		√	
Fever or signs of infection: high temperature, redness or swelling at the injection site, a cough that brings up mucous, or sore throat		√	
Severe allergic reaction (anaphylaxis / anaphylactic reactions): Allergic reactions such as trouble breathing, difficulty speaking, tightness of the chest or wheezing, tightness in the throat, rash, hives, or swelling of the lips or tongue		√	
Neuropathy: symptoms include tingling or numbness in the		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
extremities, muscle weakness, tightness or discomfort in the throat or other altered sensations. May interfere with daily activities.			
Nervous System Problems: Symptoms such as headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss		√	
Kidney failure: symptoms include difficulty breathing, weakness, fatigue, decreased urine output), small purple-red marks on the skin or other parts of the body. Kidney failure may be not reversible with discontinuation of therapy and dialysis may be required.		√	
Heart Failure (heart does not pump blood as well as it should): Irregular heartbeat, feeling dizzy, fatigue and weakness or fainting, fluid retention.		√	
Muscle Problems: Muscle pain and swelling, with weakness, fever and darkened urine		√	
Gastrointestinal Problems: Stomach pain, nausea, vomiting, black or red-coloured stools		√	
Disseminated intravascular coagulation: (Could be life-threatening). Symptoms such as: bleeding in urine or stools, small red or brown bruises that happen easily, pain and swelling in the lower leg, or chest pain and shortness of breath.		√	
Neuritis (inflammation of nerves)		√	
Focal nodular hyperplasia (non-cancerous tumor of the liver): symptoms include recent or chronic abdominal pain or discomfort, noticeable mass, weight loss, weakness, and fever)		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<p>Myelosuppression including:</p> <p>Anemia (low red blood cells): fatigue, loss of energy, pale skin, shortness of breath, weakness</p> <p>Neutropenia (low white blood cells): signs of infection such as a sore throat and high temperature</p> <p>Thrombocytopenia (low platelets): abnormal bruising, bleeding</p>		√	
Interstitial lung disease: symptoms such as rapid breathing and shortness of breath		√	
Deep vein thrombosis: (Could be life threatening). Symptoms can include leg swelling, leg pain, cramping or soreness that often starts in the calf, change in skin color on the leg, a feeling of warmth on the affected leg.,		√	
Severe liver problems: This may include issues with liver function, damage or death of liver cells. Increase in liver enzymes and alkaline phosphatase [alkaline phosphatase is an enzyme found in many parts of the body].		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Unopened vials of Oxaliplatin should be stored between 15 and 25°C. Protect from freezing.

Keep out of reach and sight of children.

If you want more information about Oxaliplatin:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <https://www.pfizer.ca> or by calling 1-800-463-6001.

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