

PART III: CONSUMER INFORMATION**^{Pr}OxALIPLATIN**

Oxaliplatin Injection, Pfizer Standard
5 mg/mL oxaliplatin

50 mg / 10 mL, 100 mg / 20 mL, 200 mg / 40 mL

Sterile concentrate for intravenous infusion
Must be diluted before administration

This leaflet is part III of a three-part “Product Monograph” published when the drug is approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Oxaliplatin. Contact your doctor, pharmacist or nurse if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

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

- colon cancer after they have undergone a surgery to remove the tumor.
- metastatic colorectal cancer.

What it does:

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

Oxaliplatin links to the genetic material contained in the cell and inhibits the replication process, causing the eventual death of the cancer cell.

When it should not be used:

Do not use Oxaliplatin if you:

- Are allergic to oxaliplatin or other platinum containing ingredients or to any of the ingredients in the product (see the section “**What the non-medicinal ingredients are**”)
- Have numbness, weakness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms
- Have a severe kidney disease
- Are breast-feeding
- Are pregnant

What the medicinal ingredient is:

oxaliplatin

What the nonmedicinal ingredients are:

Tartaric acid, sodium hydroxide and water for injection

What dosage forms it comes in:

Oxaliplatin, solution for injection (5 mg/mL) available in vials containing 50 mg / 10 mL, 100 mg / 20 mL and 200 mg / 40 mL.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

Oxaliplatin should be given under the supervision of a doctor experienced in the use of anti-cancer drugs.

Oxaliplatin may cause severe allergic reactions, liver problems, decrease in the production of blood cells, life-threatening complications due to infections, neuropathy (nerve changes) and respiratory problems (interstitial lung disease that may result in death).

Oxaliplatin may also cause the following adverse effects, which may be life-threatening: irregular heartbeats; intestinal ulcers, bleeding or perforation (a hole in the intestine wall) or a decrease in blood flow to the intestines; muscular adverse effects.

BEFORE your Oxaliplatin administration, talk to your doctor if you:

- Have ever had any unusual or allergic reaction to oxaliplatin or other medications or to platinum containing compounds
- Are taking any medicine
- Have not taken your premedication as directed
- Have a kidney disease
- Have a heart disease called “QT prolongation”
- Have recently received or plan to receive any vaccines
- Are or are planning to become pregnant. Use an effective form of birth control to keep from getting pregnant. If you think you have become pregnant while using the medicine, tell your doctor right away. Men should be advised not to father a child while receiving treatment with Oxaliplatin and up to 6 months thereafter.
- Are breast-feeding

Your doctor will need to check your blood at regular visits while you are using this medicine.

Nerves changes (neuropathy) can occur with Oxaliplatin (see the section “**Side Effect and What to Do About Them**”). Exposure to cold can trigger this side effect. 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.

Driving and operate machinery

Oxaliplatin may cause dizziness, other neurological disorders that affect balance, and vision problems including reversible short-term loss of vision. Do not drive or operate machinery until you know how the drug affects you.

INTERACTIONS WITH THIS MEDICATION

Oxaliplatin may interact with warfarin (a drug that reduces clot formation in the blood).

Before using any prescription, over-the-counter medicines or herbal products, check with your doctor, your pharmacist or your nurse.

PROPER USE OF THIS MEDICATION

Usual Dose:

Every patient is different; your doctor will determine what dose of 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 in combination with leucovorin and 5-fluorouracil (5-FU).

The administration of Oxaliplatin may require you to take medication before each treatment begins (premedication). The purpose of this premedication is to help lessen the nausea. Your doctor, nurse or pharmacist 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 doctor before you get your Oxaliplatin treatment. Be sure to keep all appointments.

Overdose:

In case of overdose, you may experience increased side effects.

If you suspect an overdose, contact a health care practitioner, 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 a dose, call your doctor for instructions.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like many chemotherapy drugs, Oxaliplatin may have side effects.

Most of the side effects that occur with oxaliplatin are manageable. Occasionally, it is necessary to stop the treatment.

Common Side Effects

- Nausea, diarrhea, vomiting, change in taste

- Fatigue
- Stomatitis: sores in the mouth
- Pain at the injection site
- Pain in a joint
- Nose bleeding
- Respiratory problems
- Hiccups
- High blood pressure
- Neuropathy: nerve changes that can cause tingling or numbness in the extremities, muscle weakness or other altered sensations.

Exposure to cold is one of the most common triggers of neuropathy. Touching cold objects or frozen items, consuming cold foods or beverages, and breathing cold air may cause these unpleasant nerve sensations (see the section “**Warnings and Precautions**”). A less common symptom of neuropathy is pharyngolaryngeal dysesthesia. This is the sensation of tightness or discomfort in the throat, making it seem difficult to breathe or swallow.

Although this symptom may be frightening, it is just a sensation and does not really interfere with breathing. The sensation usually goes away on its own after a few minutes.

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

Many of these neuropathy symptoms are temporary. However, they may continue long term.

- Neutropenia: a lower-than-normal number of neutrophils, a type of white blood cells. Your white blood cells protect your body against infection. So, if you have neutropenia, you are at higher risk of having an infection, which can be life-threatening. However, most people receiving oxaliplatin do not develop infections, even when they have neutropenia.
- Thrombocytopenia: a lower-than-normal number of platelets. Platelets have an important role in the control of bleeding. Therefore, a reduction in their number may increase the tendency to bleed
- Anemia: a lower-than-normal number of red blood cells. As a result, people with anemia may feel tired.

Your doctor will be checking routinely your blood count and will alert you if your platelets, white or red blood cells are low.

Other Possible Side Effects are:

- Constipation
- Stomach pain
- Loss of appetite
- Hair loss
- Reversible short-term loss of vision
- Deep vein thrombosis (blood clot in the deep vein)
- Interstitial lung disease (respiratory symptoms such as rapid breathing and shortness of breath)

Discuss with your doctor if you have these symptoms.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / Effect	Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
	Only if severe	In all cases	
Uncommon			
Persistent vomiting or diarrhea		√	
Persistent cough		√	
Fever or signs of infection, like redness or swelling at the injection site, a cough that brings up mucous, or sore throat		√	
Allergic reactions such as trouble breathing, tightness in the throat, rash, hives, or swelling of the lips or tongue		√	
Neuropathy symptoms interfering with daily activities		√	
Symptoms such as headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss		√	
Unknown frequency			
Kidney failure (with symptoms such as: difficulty breathing, weakness, tiredness, decreased urinary volume), 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.		√	
Irregular heartbeat, dizziness or fainting		√	
Muscle pain and swelling, with weakness, fever and darkened urine		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / Effect	Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
	Only if severe	In all cases	
Stomach pain, nausea, vomiting, black or red-coloured stools		√	
Disseminated intravascular coagulation (which may be life-threatening), with 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) with symptoms such as recent or chronic abdominal pain or discomfort, noticeable mass, weight loss, weakness, and fever)		√	

This is not a complete list of severe side effects. If you have any unexpected effects while taking this drug, contact your doctor or pharmacist.

HOW TO STORE IT

Unopened vials of Oxaliplatin should be stored between 15 and 25°C. Protect from freezing. Protection from light is not required.

Reporting Side Effects
<p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>

MORE INFORMATION

Your doctor, pharmacist and nurse are always your best source of information about your condition and treatment. If you have additional questions or concerns, be sure to ask them.

This document plus the full Product Monograph, prepared for health professionals can be found by contacting the sponsor, Pfizer Canada ULC, at: **1-800-463-6001**.

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