

Patient Information
Oxaliplatin (ox-AI-ah-platin) Injection, USP
injection for intravenous use

What is the most important information I should know about Oxaliplatin injection?

Oxaliplatin injection can cause serious allergic reactions, including allergic reactions that can lead to death. Oxaliplatin injection is a platinum-based medicine. Serious allergic reactions including death can happen in people who take Oxaliplatin injection and who have had previous allergic reactions to platinum-based medicines. Serious allergic reactions can happen within a few minutes of your Oxaliplatin injection infusion or any time during your treatment with Oxaliplatin injection.

Get emergency help right away if you:

- have trouble breathing
- feel like your throat is closing up

Call your doctor right away if you have any of the following signs or symptoms of an allergic reaction:

- rash
- flushed face
- hives
- itching
- swelling of your lips or tongue
- sudden cough
- dizziness or feel faint
- sweating
- chest pain

See “**What are the possible side effects of Oxaliplatin injection?**” for information about other serious side effects.

What is Oxaliplatin injection?

Oxaliplatin injection is an anti-cancer (chemotherapy) medicine that is used with other anti-cancer medicines called fluorouracil and leucovorin to treat people with:

- stage III colon cancer after surgery to remove the tumor
- advanced colon or rectal cancer (colorectal cancer)

It is not known if Oxaliplatin injection is effective in children.

Who should not receive Oxaliplatin injection?

Do not receive Oxaliplatin injection if you are allergic to any of the ingredients in Oxaliplatin injection or other medicines that contain platinum. See the end of this leaflet for a complete list of the ingredients Oxaliplatin injection. Ask your doctor if you are not sure if you take a medicine that contains platinum.

What should I tell my doctor before receiving Oxaliplatin injection?

Before receiving Oxaliplatin injection, tell your doctor about all of your medical conditions, including if you:

- have an infection
- have lung, liver, or kidney problems
- have bleeding problems
- have or had heart problems such as an abnormal heart test called an electrocardiogram (ECG or EKG), a condition called long QT syndrome, an irregular or slow heartbeat, or a family history of heart problems.
- have had changes in the level of certain blood salt (electrolytes) levels, including potassium, magnesium, and calcium
- are pregnant or plan to become pregnant. Oxaliplatin injection may harm your unborn baby. Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with Oxaliplatin injection.
- if you are able to become pregnant, your doctor may do a pregnancy test before you start treatment with Oxaliplatin injection and for 9 months after the final dose. Talk to your doctor about forms of birth control that may be right for you.
- Females who are able to become pregnant should avoid becoming pregnant and should use effective birth control during treatment with Oxaliplatin injection and for 9 months after the final dose. Talk to your doctor about forms of birth control that may be right for you.
- Males with female partners who are pregnant or able to become pregnant should use effective birth control during treatment with Oxaliplatin injection and for 6 months after the final dose.
- Oxaliplatin injection may cause fertility problems in males and females. Talk to your doctor if this is a concern for you.
- are breastfeeding or plan to breastfeed. It is not known if Oxaliplatin passes into your breast milk. Do not breastfeed during treatment with Oxaliplatin injection and for 3 months after the final dose.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How will I receive Oxaliplatin injection?

- Oxaliplatin injection is given to you into your vein through an intravenous (IV) tube.
- Your doctor will prescribe Oxaliplatin injection in a dose that is right for you.
- Your doctor may change how often you receive Oxaliplatin injection, your dose, or how long your infusion will take.
- You and your doctor will decide how many Oxaliplatin injection treatments you will receive.
- It is very important that you do exactly what your doctor and nurse tell you to do.
- Some medicines may be given to you before Oxaliplatin injection to help prevent nausea and vomiting.
- Each treatment course is given to you over 2 days. You will receive Oxaliplatin injection on the first day only.
- There are usually 14 days between each chemotherapy treatment course.
- It is important for you to keep all of your medical appointments. Call your doctor if you miss an appointment. There may be special instructions for you.

Treatment Day 1:

- Oxaliplatin injection and leucovorin will be given through a thin plastic tube into a vein (intravenous infusion or IV) and given for 2 hours. You will be watched by a healthcare provider during this time.
- Right after the Oxaliplatin injection and leucovorin are given, 2 doses of fluorouracil will be given. The first dose is given right away into your IV tube. The second dose will be given into your IV tube over the next 22 hours, using a pump device.

Treatment Day 2:

You **will not** get Oxaliplatin injection on Day 2. Leucovorin and fluorouracil will be given the same way as on Day 1.

The fluorouracil will be given through your IV with a pump. If you have any problems with the pump or the tube, call your doctor, your nurse, or the person who is responsible for your pump. Do not let anyone other than a healthcare provider touch your infusion pump or tubing.

What should I avoid while receiving Oxaliplatin injection?

- Avoid cold temperatures and cold objects. Cover your skin if you go outdoors in cold temperatures.
- Do not drink cold drinks or use ice cubes in drinks.
- Do not put ice or ice packs on your body.
- Oxaliplatin injection can cause dizziness, vision problems, or vision loss that can affect your ability to drive or use machines. You should not drive or operate machinery if you develop these symptoms while receiving Oxaliplatin injection.

See “**How can I reduce the side effects caused by cold temperatures?**” for more information.

Talk with your doctor and nurse about your level of activity during treatment with Oxaliplatin injection. Follow their instructions.

What are the possible side effects of Oxaliplatin injection?

Oxaliplatin injection can cause serious side effects, including:

- See “**What is the most important information I should know about Oxaliplatin injection?**”
- **Nerve problems.** Oxaliplatin injection can affect how your nerves work and make you feel. Nerve problems may happen with the first treatment or within two days after your treatment of Oxaliplatin injection. Nerve problems may last a short time (acute) or may become persistent. Symptoms may improve after stopping treatment with Oxaliplatin injection. Exposure to cold or cold objects may cause or worsen nerve problems. Tell your doctor right away if you get any signs of nerve problems, including:
 - very sensitive to cold temperatures and cold objects
 - trouble breathing, swallowing, or saying words, jaw tightness, odd feelings in your tongue, or chest pressure

- pain, tingling, burning (pins and needles, numb feeling) in your hands, feet, or around your mouth or throat, which may cause problems walking, fall ,or performing activities of daily living

For information on ways to lessen or help with the nerve problems, see the end of this leaflet, “**How can I reduce the side effects caused by cold temperatures?**”

- **Posterior Reversible Encephalopathy Syndrome (PRES).** PRES is a rare condition that affects the brain. Tell your doctor right away if you have any of the following signs and symptoms of PRES:
 - headache
 - confusion or a change in the way you think
 - seizures
 - vision problems, such as blurriness or vision loss
- **Low blood cell counts (myelosuppression).** Oxaliplatin injection when used with fluorouracil and leucovorin can cause low blood cells counts. Low blood cell counts are common with Oxaliplatin injection when used with fluorouracil and leucovorin and can lead to serious infection and death. Tell your doctor right away if you have a fever greater than 100.9°F (38.3°C) or a prolonged fever greater than 100.4°F (38°C) for more than one hour (febrile neutropenia). Call your doctor right away if you get any of the following signs of infection:

○ chills or shivering	○ burning or pain on urination
○ pain on swallowing	○ redness or swelling at intravenous site
○ sore throat	○ persistent diarrhea
○ cough that brings up mucus	
- **Risk of new cancers.** Leukemia, a form of blood cancer, has been reported in patients after taking Oxaliplatin injection in combination with certain other medicines. Talk to your doctor about the potential for increased risk of this type of cancer when taking Oxaliplatin injection and certain other medicines.
- **Lung Problems.** Oxaliplatin injection can cause lung problems that may lead to death. Tell your doctor right away if you get any of the following symptoms as these may be indicators of a serious lung disease:

○ shortness of breath	○ cough
○ wheezing	
- **Liver problems (hepatotoxicity).** Your doctor will do blood tests to check your liver when you start receiving Oxaliplatin injection, and before each treatment course as needed.
- **Heart problems.** Oxaliplatin injection can cause heart problems that have led to death. Your doctor may do blood and heart tests during treatment with Oxaliplatin injection if you have certain heart problems. If you faint (lose consciousness) or have an irregular heartbeat or chest pain during treatment with Oxaliplatin injection, get medical help right away as this may be a sign of a serious heart condition.
- **Muscle problems.** Oxaliplatin injection can cause muscle damage (rhabdomyolysis) which can lead to death. Tell your doctor right away if you have muscle pain and swelling, along with weakness, fever, or red-brown urine.
- **Harm to an unborn baby.** See “**What should I tell my doctor before receiving Oxaliplatin injection?**”
- **Bleeding problems (hemorrhage).** Oxaliplatin injection when used with fluorouracil and leucovorin can cause bleeding problems (hemorrhage) that can lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs or symptoms of bleeding, including:

○ blood in your stools or black stools (looks like tar)	○ increased bruising
○ pink or brown urine	○ dizziness
○ unexpected bleeding, or bleeding that is severe or you cannot control	○ weakness
○ vomit blood or vomit that looks like coffee grounds	○ confusion
○ cough up blood or blood clots	○ changes in speech
	○ headache that lasts a long time

The most common side effects of Oxaliplatin injection include:

- numbness, pain, tingling, and/or burning along the nerves
- low white blood cells (blood cells important for fighting infection)
- low platelet count (important for clotting and to control bleeding)

- low red blood cells (blood cells that carry oxygen to the tissues)
- nausea
- changes in liver function tests
- diarrhea
- vomiting
- tiredness
- mouth sores

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Oxaliplatin injection. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How can I reduce the side effects caused by cold temperatures?

- Cover yourself with a blanket while you are getting your Oxaliplatin injection infusion.
- Do not breathe deeply when exposed to cold air.
- Wear warm clothing in cold weather at all times. Cover your mouth and nose with a scarf or a pull-down cap (ski cap) to warm the air that goes to your lungs.
- Wear gloves when taking things from the freezer or refrigerator.
- Drink fluids warm or at room temperature.
- Always drink through a straw.
- **Do not** use ice chips if you have nausea or mouth sores. Ask your doctor about what you can use.
- Be aware that most metals are cold to touch, especially in the winter. These include your car door and mailbox. Wear gloves to touch cold objects.
- Do not run the air-conditioning at high levels in the house or in the car in hot weather.
- If your body gets cold, warm-up the affected part. If your hands get cold, wash them with warm water.
- Always let your doctor know **before** your next treatment how well you did since your last visit.

Your doctor may have other useful tips for helping you with side effects.

General information about the safe and effective use of Oxaliplatin injection Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. This Patient Information leaflet summarizes the most important information about Oxaliplatin injection. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Oxaliplatin injection that is written for health professionals.

What are the ingredients in Oxaliplatin injection?

Active ingredient: oxaliplatin

Inactive ingredient: water for injection

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