

Oxaliplatin Cas No. : 61825-94-3

This medication is used to treat advanced cancer of the colon and rectum. Oxaliplatin is a chemotherapy drug that contains platinum. It is used in combination with other medications to slow or stop cancer cell growth.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Oxaliplatin

CAS No. : 61825-94-3

**Synonyms**

trans-L-Diaminocyclohexane oxalatoplatinum

CAS Registry Number 61825-94-3

Molecular Formula C₈H₁₂N₂O₄Pt

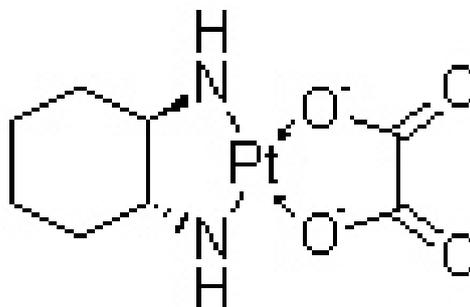
Molecular Weight 395.27

Molecular Structure Oxaliplatin, trans-L-Diaminocyclohexane oxalatoplatinum,

Chemical data

Formula C₈H₁₄N₂O₄Pt

Mol. mass 397.2858 g/mol

**Pharmacokinetic data**

Bioavailability Complete

Metabolism ?

Half life ~10 - 25 minutes [1]

Excretion Renal

DOSAGE**Oxaliplatin may be given:**

* by injection into a vein (intravenously), through a fine tube (cannula) inserted into the vein

* through a central line, which is inserted under the skin into a vein near the collarbone, or into a PICC line, which is inserted into a vein in the crook of the arm.

Chemotherapy is usually given as a course of several sessions (or cycles) of treatment over a few months. The length of your treatment and the number of cycles you have will depend on the type of cancer for which you are being treated. Your nurse or doctor will discuss your treatment plan with you.

Oxaliplatin in combination with 5-FU/LV every 2 weeks. For advanced disease, treatment is recommended until disease progression or unacceptable toxicity. For adjuvant use, treatment is recommended for a total of 6 months (12 cycles):

Day 1: Oxaliplatin 85 mg/m² IV infusion in 250-500 mL 5% Dextrose injection, USP (D5W) and Oxaliplatin 200 mg/m² IV infusion in D5W both given over 120 minutes at the same time in separate bags using a Y-line, followed by 5-FU 400 mg/m² IV bolus given over 2-4 minutes, followed by 5-FU 600 mg/m² IV infusion in 500 mL D5W (recommended) as a 22-hour continuous infusion.

Day 2: Oxaliplatin 200 mg/m² IV infusion over 120 minutes, followed by 5-FU 400 mg/m² IV bolus given over 2-4 minutes, followed by 5-FU 600 mg/m² IV infusion in 500 mL D5W (recommended) as a 22-hour continuous infusion.



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SIDE EFFECTS

Each person's reaction to chemotherapy is different. Some people have very few side effects, while others experience more. The side effects described in this information will not affect everyone who is given oxaliplatin and may be different if you are having more than one chemotherapy drug. We have outlined the most common side effects as well as rarer ones, so that you can be aware of them if they occur. However, we have not included those that are very rare and therefore extremely unlikely to affect you. If you notice any effects which you think may be due to the drug, but which are not listed in this information, please discuss them with your doctor or chemotherapy nurse.

Numbness or tingling in hands or feet Oxaliplatin can have an effect on the nerve endings, which is known as peripheral neuropathy. This may result in feelings of numbness or tingling, especially in the hands, feet, neck or throat. For some people, these symptoms can be triggered by anything cold, such as iced drinks and cold air. If you notice that your symptoms are related to the cold you should avoid cold drinks and wrap up warmly in the cold weather. It is important to report your symptoms to your doctor as they may be controlled by slightly lowering the dose of the drug. Sometimes the tingling or numbness may not happen with the first treatment, but after several treatments. This is known as a 'cumulative effect' and should improve after the treatment has finished.

Lowered resistance to infection Oxaliplatin can reduce the production of white blood cells by the bone marrow, making you more prone to infection. This effect can begin seven days after treatment has been given. Your blood cells will then increase steadily and will usually have returned to normal before your next cycle of chemotherapy is due.

Contact your doctor or the hospital straightaway if:

- * your temperature goes above 38°C (100.5°F)
- * you suddenly feel unwell (even with a normal temperature).

You will have a blood test before having more chemotherapy to make sure that your cells have recovered. Occasionally it may be necessary to delay your treatment if the number of blood cells (the blood count) is still low.

Bruising or bleeding Oxaliplatin can reduce the production of platelets (which help the blood to clot). Let your doctor know if you have any unexplained bruising or bleeding, such as nosebleeds, blood spots or rashes on the skin, or bleeding gums. **Anaemia** (low number of red blood cells) While having treatment with oxaliplatin you may become anaemic. This may make you feel tired and breathless. Let your doctor or nurse know if these symptoms are a problem. **Feeling sick (nausea) and being sick (vomiting)** If you do feel sick this may begin a few hours after the treatment is given and last for a few days. Your doctor can prescribe very effective anti-sickness (anti-emetic) drugs to prevent, or greatly reduce, nausea and vomiting. If the sickness is not controlled, or continues, tell your doctor; they can prescribe other anti-sickness drugs which may be more effective. Some anti-sickness drugs can cause constipation. Let your doctor or nurse know if this is a problem.

Diarrhoea This can usually be easily controlled with medicine but tell your doctor if it is severe or if it continues. It is important to drink plenty of fluids if you have diarrhoea.

Tiredness and feeling weak You may feel very tired. It is important to allow yourself plenty of time to rest.

PRECAUTIONS

Before using oxaliplatin,

- * tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention oral anticoagulants ('blood thinners') such as warfarin (Coumadin). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- * tell your doctor if you have or have ever had kidney disease.
- * tell your doctor if you are pregnant or plan to become pregnant. Oxaliplatin may harm the fetus. You should use birth control to prevent pregnancy during your treatment with oxaliplatin. Talk to your doctor about types of birth control that will work for you. If you become pregnant while taking oxaliplatin, call your doctor.



Do not breast-feed during your treatment with oxaliplatin.
* if you are having surgery, including dental surgery, tell the doctor or dentist that you are using oxaliplatin.
* you should know that oxaliplatin may decrease your ability to fight infection. Stay away from people who are sick during your treatment with oxaliplatin.
* you should know that exposure to cold air or objects may make some of the side effects of oxaliplatin worse. You should not eat or drink anything colder than room temperature, touch any cold objects, go near air conditioners or freezers, wash your hands in cold water, or go outside in cold weather unless absolutely necessary for five days after you receive each dose of oxaliplatin. If you must go outside in cold weather, wear a hat, gloves, and a scarf, and cover your mouth and nose.



DRUG DESCRIPTION

Oxaliplatin is a chemotherapy drug that is given as a treatment for some types of cancer. It is most commonly used to treat cancer of the large bowel. This information describes oxaliplatin, how it is given and some of its possible side effects. It should ideally be read with our general information about chemotherapy. Oxaliplatin is a colourless fluid. Oxaliplatin is a platinum-based chemotherapy drug in the same family as cisplatin and carboplatin. It is typically administered in combination with fluorouracil and leucovorin in a combination for the treatment of colorectal cancer. Oxaliplatin is used with other medications to treat advanced colon or rectal cancer (cancer that begins in the large intestine). Oxaliplatin is also used with other medications to prevent colon cancer from spreading in people who have had surgery to remove the tumor. Oxaliplatin is in a class of medications called platinum-containing antineoplastic agents. It works by killing cancer cells. Oxaliplatin comes as a solution (liquid) to be injected into a vein. Oxaliplatin is administered by a doctor or nurse. It is usually given once every fourteen days.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:

91 022 30601000.

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