

PATIENT INFORMATION

ELOXATIN[®] (OXALiPlatin for injection) and ELOXATIN[®] (OXALiPlatin injection) INJECTION

Read this information carefully as you start using ELOXATIN. It will help you learn more about ELOXATIN. This information does not take the place of talking to your doctor about your medical condition or your treatment. Ask your doctor about any questions you have.

What is ELOXATIN?

ELOXATIN (eh-LOX-ah-tin) is an anticancer (chemotherapy) medicine that is used:

- to treat adults with stage III colon cancer after surgery to remove the tumor.
- with other anti-cancer medicines called 5-fluorouracil (5-FU) and leucovorin (LV) to treat adults with advanced colon or rectal cancer (colo-rectal cancer).

ELOXATIN with infusional 5-FU and LV was shown to lower the chance of colon cancer returning when given to patients with stage III colon cancer after surgery to remove the tumor. It is not known if ELOXATIN increases survival in patients with stage III colon cancer. ELOXATIN with infusional 5-FU and LV was also shown to increase survival, shrink tumors and delay growth of tumors in some patients with advanced colorectal cancer.”

The use of ELOXATIN in children has not been studied.

Who should not use ELOXATIN?

Do not use ELOXATIN if:

- You are allergic to platinum. The active ingredient in ELOXATIN is oxaliplatin, which is a platinum-containing drug. Cisplatin (Platinol[®]) and carboplatin (Paraplatin[®]) are other chemotherapy medicines that also contain platinum.
- You are pregnant. ELOXATIN may harm your unborn child. You should avoid becoming pregnant while taking ELOXATIN. Talk with your doctor about how to avoid pregnancy.

Tell your doctor:

- You are breast feeding. We do not know if ELOXATIN can pass through your milk and if it can harm your baby. You will need to decide whether to stop breast feeding or not to take ELOXATIN.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines and herbal supplements. ELOXATIN may affect how they work in your body.

How is ELOXATIN given to me?

ELOXATIN is given to you through your veins (blood vessels).

Your doctor will prescribe ELOXATIN in an amount that is appropriate for you. Your doctor will treat you with several medicines for your cancer. It is very important that you do exactly what your doctor and nurse have taught you to do. Some medicines may be given to you before ELOXATIN to help prevent nausea and vomiting.

ELOXATIN is given with 2 other chemotherapy drugs, leucovorin and 5-FU. Each treatment course is given to you over 2 days. You will receive ELOXATIN on the first day only. There are usually 14 days between each chemotherapy treatment course.

Treatment Day 1:

ELOXATIN and leucovorin are put into a vein through a thin plastic tube (intravenous infusion or I.V.) and given for 2 hours. You will be watched by a healthcare provider during this time.

Right after the ELOXATIN and leucovorin are finished, 2 doses of 5-FU will be given. The first dose is given right away into your I.V. tube. The second dose will be given into your I.V. tube over the next 22 hours, using a pump device.

Treatment Day 2:

You will not get ELOXATIN on Day 2. Leucovorin and 5-FU will be given the same way as on Day 1.

During your treatment with ELOXATIN:

- It is important for you to keep all appointments. Call your doctor if you must miss an appointment. There may be special instructions for you.
- Your doctor may change how often you get ELOXATIN, how much you get, or how long the infusion will take.
- You and your doctor will discuss how many times you will get ELOXATIN.

The 5-FU will be given through your I.V. 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. You should never allow anyone other than a healthcare provider to touch your infusion pump or tubing.

What activities should I avoid while under treatment with ELOTAXIN?

- Avoid cold temperatures and cold objects. Cover your skin if you must go outside in cold temperatures.
- Do not drink cold drinks or use ice cubes in drinks.
- Do not put ice or ice packs on your body.

See the end of this leaflet, ("How I can help reduce the side effects caused by cold temperatures?")

You need to discuss your level of activity during treatment with your doctor and your nurse. You should follow their advice.

What are the possible side effects of ELOXATIN?

ELOXATIN can cause allergic reactions.

Get emergency help right away if:

- You suddenly have trouble breathing.
- Your throat feels like it is closing up.

Call your doctor right away if you have any of the following:

- Other signs of allergic reaction
 - Rash
 - Hives
 - Swelling of your lips or tongue
 - Sudden cough

Call your doctor if you get any of the following:

- Fever or signs of infection (redness and swelling at the intravenous site, pain on swallowing, cough that brings up mucous, sore throat, shivering, pain on urination)
- Vomiting that is persistent
- Diarrhea (frequent, loose, watery bowel movements)
- Signs of dehydration (too much water loss)
 - Tiredness
 - Thirst
 - Dry mouth
 - Lightheadedness (dizziness)
 - Decreased urination

Tell your doctor if you get a dry cough and have trouble breathing (shortness of breath) before your next treatment. These may be signs of a serious lung disease.

ELOXATIN can affect how your nerves work and make you feel (peripheral neuropathy). Tell your doctor right away, if you get any signs of nerve problems listed below:

- 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 or performing activities of daily living

The first signs of nerve problems may occur with the initial treatment. The nerve problems can also start up to 2 days afterwards. If you develop nerve problems, the amount of ELOXATIN in your next treatment may be changed.

For information on ways to lessen or help with the nerve problems see the end of this leaflet, "How I can help reduce the side effects caused by cold temperatures?" Other common side effects from ELOXATIN include nausea, vomiting, diarrhea, constipation, mouth sores, stomach pain, fever, loss of appetite, and tiredness.

These are not all the possible side effects of ELOXATIN. For more information, ask your doctor or pharmacist.

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

- Cover yourself with a blanket while you are getting your ELOXATIN 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.
- Don't take things from the freezer or refrigerator without wearing gloves.
- 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 nurse 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 nurse and doctor know **before** your next treatment how well you did since your last visit.

This list is not complete and your healthcare provider may have other useful tips for helping you with these side effects.

General Information about the safe and effective use of ELOXATIN.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets.

This leaflet summarizes the most important information about ELOXATIN. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ELOXATIN that is written for health professionals.

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/s/

Robert Justice
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