

**C**hemotherapy may lower the number of white blood cells you normally have to fight infection, so it's important to try to take extra care of yourself to avoid infection. Even normally-occurring bacteria that are part of a healthy life can cause infection if you have fewer white blood cells than normal.

**Here are some ways to reduce the chances of getting an infection:**

- Wash your hands often, and always before you eat, after going to the bathroom, and after touching animals
- Wear protective gloves when gardening or cleaning up after people
- Clean cuts and scrapes daily until they've healed
- Treat the skin with lotion or oil if it becomes dry and cracked
- Wash with warm (not hot) water daily, and gently pat skin dry
- Use an electric shaver—not a razor—if you need to shave so you can avoid cutting the skin
- Make sure to thoroughly clean yourself after every bowel movement
- Don't rip or cut cuticles
- Don't pick or scratch acne
- To help reduce bacteria in the mouth, brush your teeth frequently but gently



**You should also avoid the following to help prevent infection:**

- Crowds
- Children who recently received “live virus” vaccinations such as chicken pox or oral polio
- People with colds, the flu, measles, chicken pox, or other contagious diseases
- Standing water—like bird baths, flower vases, or humidifiers
- Litter boxes, bird cages, fish tanks—or their waste
- Eating undercooked or raw eggs, meat, seafood, and fish

**When to talk to your doctor:**

Certain otherwise normal activities can cause infections. Tell your doctor if you have any signs of infection and ask your doctor first before using enemas or suppositories, or before getting any immunizations.

***Do not take any medication for infection or fever without first talking to your doctor.***

**Some signs of infection**

- Fever over 100°F
- Chills
- Sweating
- Loose stool
- Frequent urgent or burning urination
- Cough or sore throat that's severe
- Itching or unusual discharge from the vagina
- Pressure or pain in the sinuses
- Stiff neck
- Earaches or headaches
- Blisters
- Mouth sores
- Redness, swelling, or tenderness in any part of the skin

## Indications and Usage

Eloxatin® (oxaliplatin injection), used in combination with infusional 5-FU/LV, is indicated for

- Adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor. The indication is based on an improvement in disease-free survival, with no demonstrated benefit in overall survival after a median follow-up of 4 years
- Treatment of advanced carcinoma of the colon or rectum

## Clinical Safety Considerations

**ELOXATIN should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.**

**Anaphylactic-like reactions to ELOXATIN have been reported and may occur within minutes of ELOXATIN administration. Epinephrine, corticosteroids, and antihistamines have been employed to alleviate symptoms, and discontinuation of ELOXATIN therapy may be required.**

- ELOXATIN should not be administered to patients with a history of known allergy to ELOXATIN or other platinum compounds. Hypersensitivity and anaphylactic/anaphylactoid reactions to ELOXATIN have been reported and were similar in nature and severity to those reported with other platinum compounds (ie, rash, urticaria, erythema, pruritus, and, rarely, bronchospasm and hypotension). These reactions occur within minutes of administration and should be managed with appropriate supportive therapy. Drug-related deaths from this reaction have been reported
- ELOXATIN may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant while receiving ELOXATIN. It is not known whether ELOXATIN or its derivatives are excreted in human milk
- ELOXATIN has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal. The combined incidence of cough and dyspnea was 7.4% (<1% grade 3, no grade 4) in the ELOXATIN plus 5-FU/LV arm compared to 4.5% (no grade 3, 0.1% grade 4) in the 5-FU/LV alone arm in the adjuvant colon cancer study. In this study, one patient died from eosinophilic pneumonia in the ELOXATIN combination arm. The combined incidence of cough, dyspnea, and hypoxia was 43% (7% grade 3 and 4) in the ELOXATIN plus 5-FU/LV arm compared to 32% (5% grade 3 and 4) in the irinotecan plus 5-FU/LV arm in patients with previously untreated colorectal cancer. In case of unexplained respiratory symptoms, ELOXATIN should be discontinued until pulmonary investigation excludes interstitial lung disease or pulmonary fibrosis
- ELOXATIN is associated with two types of primarily peripheral sensory neuropathy: an

acute, reversible type of early onset and a persistent type (>14 days). In patients with advanced colorectal cancer, paresthesias occurred in 77% (all grades) and 18% (grade 3/4) of previously untreated patients. In previously treated patients, acute neuropathy occurred in 56% (all grades) and 2% (grade 3/4) of patients; persistent neuropathy occurred in 48% (all grades) and 6% (grade 3/4) of patients. In patients with stage II and III colon cancer, paresthesia was seen in 92% (all grades) and 13% (grade 3/4) of patients; 21% (all grades) and 0.5% (grade 3/4) of patients had residual paresthesia at 18-month follow-up

- Hepatotoxicity, as evidenced in the adjuvant study by increase in transaminases and alkaline phosphatase, was observed more commonly in the ELOXATIN combination arm. The incidence of increased bilirubin was similar on both arms. Changes noted on liver biopsies include: peliosis, nodular regenerative hyperplasia or sinusoidal alterations, perisinusoidal fibrosis, and veno-occlusive lesions. Hepatic vascular disorders should be considered and, if appropriate, investigated in case of abnormal liver function test results or portal hypertension not explained by liver metastases
- Monitoring of white blood cell count with differential, hemoglobin, platelet count, and blood chemistries (including ALT, AST, bilirubin, and creatinine) is recommended before each ELOXATIN cycle
- The safety and effectiveness of ELOXATIN plus 5-FU/LV in patients with renal impairment have not been evaluated. Since the primary route of platinum elimination is renal, this combination should be used with caution in patients with preexisting renal impairment. Clearance of these products may be decreased by coadministration of potentially nephrotoxic compounds, although this has not been specifically studied
- The incidence of diarrhea, dehydration, hypokalemia, leukopenia, fatigue, and syncope was higher in patients ≥65 years old
- Extravasation may result in local pain and inflammation that may be severe and lead to complications, including necrosis. Injection site reaction, including redness, swelling, and pain, has been reported
- There have been reports of prolonged prothrombin time and INR occasionally associated with hemorrhage in patients receiving ELOXATIN plus 5-FU/LV while on anticoagulants. Patients receiving ELOXATIN plus 5-FU/LV and requiring oral anticoagulants may require closer monitoring
- The most common adverse reactions in patients with stage II or III colon cancer receiving adjuvant therapy were peripheral sensory neuropathy, neutropenia, thrombocytopenia, anemia, nausea, increase in transaminases and alkaline phosphatase, diarrhea, emesis, fatigue, and stomatitis. The most common adverse reactions in patients with advanced colorectal cancer were peripheral sensory neuropathy, fatigue, neutropenia, nausea, emesis, and diarrhea



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**Eloxatin**®  
(OXALIPLATIN injection)