

In the course of treatment, you should ask your health-care team any questions you may have about chemotherapy. You should also let them know of any symptoms, too.

Special doctors work with cancer patients, and there are many kinds

- **Oncologist:** A doctor who specializes in treating people with cancer
- **Hematologist:** A doctor who specializes in the study and treatment of blood diseases
- **Pathologist:** A doctor who specializes in the study of cells and tissues, such as tumors
- **Radiation oncologist:** A doctor who specializes in using radiation to treat cancer
- **Radiologist:** A doctor who specializes in making and explaining pictures of areas inside the body using x-rays and similar tests
- **Surgeon:** A doctor who specializes in operations

Other members of your health-care team might include:

- **Pharmacists**, who dispense prescribed medication
- **Nutritionists**, also called dietitians, who help with dietary decisions
- **Nurses**—oncology nurses treat cancer patients, and often give chemotherapy

It's important to deal with how you feel both emotionally and physically during and after your treatment. You can address your feelings with the medical team, and you can also meet with a counselor, a member of the clergy, or a social worker to talk about how you feel. You can also talk to a social worker in the hospital about ways to get financial aid, transportation, home care, and emotional support.



Please see full prescribing information, including Boxed WARNING, enclosed in kit.

Eloxatin[®]
(OXALIPLATIN injection)

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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