Oxaliplatin Injection, USP

50 mg per 10 mL | NDC 70860-201-10
100 mg per 20 mL | NDC 70860-201-20

ATHENEX AccuraSEE™ PACKAGING AND LABELING

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DIFFERENTIATION IN EVERY LABEL, DESIGNED TO HELP REDUCE MEDICATION ERRORS

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR OXALIPLATIN INJECTION, USP, ENCLOSED.

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### Oxaliplatin Injection, USP

#### 50 mg per 10 mL

<table>
<thead>
<tr>
<th>Description</th>
<th>Glass Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>5 mg per mL</td>
</tr>
<tr>
<td>Closure</td>
<td>20 mm</td>
</tr>
<tr>
<td>Unit of Sale</td>
<td>1 vial</td>
</tr>
<tr>
<td>Bar Code</td>
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</tbody>
</table>

#### 100 mg per 20 mL

<table>
<thead>
<tr>
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OXALIPLATIN Injection, USP

INDICATION AND USAGE

• Oxaliplatin Injection, USP used in combination with infusional 5-fluorouracil/leucovorin, is indicated for:
  • adjuvant treatment of stage III colon cancer in patients who have undergone complete resection of the primary tumor.
  • treatment of advanced colorectal cancer.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLACTIC REACTIONS

Anaphylactic reactions to Oxaliplatin Injection, USP have been reported, and may occur within minutes of Oxaliplatin Injection, USP administration. Epinephrine, corticosteroids, and antihistamines have been employed to alleviate symptoms of anaphylaxis [see Warnings and Precautions].

CONTRAINDICATIONS

Oxaliplatin Injection, USP should not be administered to patients with a history of known allergy to Oxaliplatin Injection, USP or other platinum compound.

WARNINGS AND PRECAUTIONS

• Allergic Reactions: Monitor for development of rash, urticaria, erythema, pruritis, bronchospasm, and hypotension. Drug-related deaths associated with platinum compounds from anaphylaxis have been reported.

• Neuropathy: Reduce the dose or discontinue Oxaliplatin Injection, USP if necessary. An acute, reversible, primarily peripheral, sensory neuropathy that is of early onset, occurring within hours or one to two days of dosing, that resolves within 14 days, and that frequently recurs with further dosing. A persistent (>14 days), primarily peripheral, sensory neuropathy that is usually characterized by paresthesias, dysesthesias, hypoesthesias, but may also include deficits in proprioception that can interfere with daily activities.

• Severe Neutropenia: Grade 3 or 4 neutropenia occurred in 41 to 44% of patients with colorectal cancer treated with Oxaliplatin Injection, USP in combination with 5-fluorouracil (5-FU) and leucovorin compared to 5% with 5-FU plus leucovorin alone. Sepsis, neutropenic sepsis and septic shock have been reported in patients treated with Oxaliplatin Injection, USP, including fatal outcomes. Delay Oxaliplatin Injection, USP until neutrophils are ≥1.5 x 10⁹/L. Withhold Oxaliplatin Injection, USP for sepsis or septic shock. Dose reduce Oxaliplatin Injection, USP after recovery from Grade 4 neutropenia. Oxaliplatin injection, USP has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal.

• Hepatotoxicity: Monitor liver function tests.

• Cardiovascular Toxicity: Oxaliplatin has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal. QT prolongation and ventricular arrhythmias including fatal Torsade de Pointes have been reported in postmarketing experiences following Oxaliplatin administration. ECG monitoring is recommended if therapy is initiated in patients with congestive heart failure, bradycardiac, and abnormal QTc intervals. Class IA and III antiarrhythmics, and electrolyte abnormalities. Correct hypokalemia or hypomagnesemia prior to initiating Oxaliplatin and monitor these electrolytes periodically during therapy. Avoid Oxaliplatin Injection, USP in patients with congenital long QT syndrome.

• Rhombomyolysis, including fatal cases, has been reported in patients treated with Oxaliplatin. Discontinue Oxaliplatin if rhombomyolysis occurs.

• Pregnancy. Fetal harm can occur when administered to a pregnant woman. Women should be apprised of the potential harm to the fetus.

• Recommended Laboratory Tests: Standard monitoring of the white blood cell count with differential, hemoglobin, platelet count, and blood chemistries (including ALT, AST, bilirubin and creatinine) is recommended before each Oxaliplatin Injection, USP cycle.

ADVERSE REACTIONS

• Most common adverse reactions (incidence ≥40%) were peripheral sensory neuropathy, neutropenia, thrombocytopenia, anemia, nausea, increase in transaminases and alkaline phosphatase, diarrhea, emesis, fatigue and stomatitis.

• Serious adverse reactions, including anaphylaxis and allergic reactions, neuropathy, severe neutropenia, pulmonary toxicities, hepatotoxicity, cardiovascular toxicities and rhabdomyolysis can occur.

OVERDOSAGE

• There is no known antidote for Oxaliplatin overdose. In addition thrombocytopenia, the anticipated complication of an oxaliplatin overdose include hypersensitivity reaction, myelosuppression, nausea, vomiting, diarrhea and neurotoxicity.

• Patients suspected of receiving an overdose should be monitored, and supportive treatment should be administered. The maximum dose of oxaliplatin that has been administered in a high infusion is 825 mg. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for OXALIPLATIN Injection, USP.