Oxaliplat®

Oxaliplatin USP

Presentation

Oxaliplat® 50: It is supplied in vial containing 50 mg of oxaliplatin as a sterile, preservative-free lyophilized powder for reconstitution.
Oxaliplat® 100: It is supplied in vial containing 100 mg of oxaliplatin as a sterile, preservative-free lyophilized powder for reconstitution.

Indication

Oxaliplatin is a platinum-based drug used in combination with infusional 5- fluorouracil /leucovorin, which 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.

Dosage and Administration

Administer Oxaliplatin in combination with 5-fluorouracil/leucovorin every 2 weeks. :
Day 1: Oxaliplatin 85 mg/m^2 intravenous infusion in 250-500 ml 5% Dextrose Injection, USP and leucovorin 200 mg/m^2 intravenous infusion in 5% Dextrose Injection, USP both given over 120 minutes at the same time in separate bags using a Y-line, followed by 5-fluorouracil 400 mg/m^2 intravenous bolus given over 2-4 minutes, followed by 5-fluorouracil 600 mg/m^2 intravenous infusion in 500 ml 5% Dextrose Injection, USP (recommended) as a 22-hour continuous infusion.
Day 2: Leucovorin 200 mg/m^2 intravenous infusion over 120 minutes, followed by 5-fluorouracil 400 mg/m^2 IV bolus given over 2-4 minutes, followed by 5-fluorouracil 600 mg/m^2 intravenous infusion in 500 ml 5% Dextrose Injection, USP (recommended) as a 22-hour continuous infusion.
• Reduce the dose of Oxaliplatin to 75 mg/m^2 (adjuvant setting) or 65 mg/m^2 (advanced colorectal cancer): If there are persistent grade 2 neurosensory events that do not resolve. After recovery from grade 3/4 gastrointestinal toxicities (despite prophylactic treatment) or grade 4 neutropenia or grade 3/4 thrombocytopenia. Delay next dose until neutrophils ≥1.5 x 109 /L and platelets ≥75 x 109 /L.

Contraindications

Known allergy to Oxaliplatin or other platinum compounds.

Precautions

• Allergic Reactions: Monitor for development of rash, urticaria, erythema, pruritis, bronchospasm, and hypotension.
• Neuropathy: Reduce the dose or discontinue OXALIPLATIN if necessary.
• Pulmonary Toxicity: May need to discontinue Oxaliplatin until interstitial lung disease or pulmonary fibrosis are excluded.
• Hepatotoxicity: Monitor liver function tests.
• Pregnancy: Fetal harm can occur when administered to a pregnant woman. Women should be apprised of the potential harm to the fetus.

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. Other adverse reactions, including serious adverse reactions, have been reported.

Drug Interactions

No specific cytochrome P-450 based drug interaction studies have been conducted. No pharmacokinetic interaction between 85 mg/m^2 Oxaliplatin and 5-fluorouracil/leucovorin has been observed in patients treated every 2 weeks. Increases of 5-fluorouracil plasma concentrations by approximately 20% have been observed with doses of 130 mg/m^2 Oxaliplatin doses every 3 weeks. Because platinum-containing species are eliminated primarily through the kidney, clearance of these products may be decreased by coadministration of potentially nephrotoxic compounds; although, this has not been specifically studied.

Pregnancy

Pregnancy Category D

Nursing Mothers

It is not known whether Oxaliplatin or its derivatives are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Oxaliplatin, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The effectiveness of oxaliplatin in children has not been established. Oxaliplatin has been tested in 2 Phase, 1 and 2 Phase 2 trials in 235 patients ages 7 months to 22 years with solid tumors and no significant activity observed.

Geriatric

Use No significant effect of age on the clearance of ultrafilterable platinum has been observed.

Patients with Renal Impairment

The exposure (AUC) of unbound platinum in plasma ultrafiltrate tends to increase in renally impaired patients. Caution and close monitoring should be exercised when Oxaliplatin is administered to patients with renal impairment. The starting Oxaliplatin dose does not need to be reduced in patients with mild (creatinine clearance=50-80 ml/min) or moderate (creatinine clearance=30-49 ml/min) renal impairment. However, the starting dose of Oxaliplatin should be reduced in patients with severe renal impairment (creatinine clearance < 30 ml/min) [see Dosage and Administration].

Overdosage

There is no known antidote for Oxaliplatin overdose. In addition to thrombocytopenia, the anticipated complications of an Oxaliplatin overdose include hypersensitivity reaction, myelosuppression, nausea, vomiting, diarrhea and neurotoxicity. Several cases of overdoses have been reported with Oxaliplatin. Adverse reactions observed were Grade 4 thrombocytopenia. Adverse reactions observed were Grade 4 thrombocytopenia (Adver Adverse reactions observed were Grade 4 thrombocytopenia (<25,000/mm^3) without any bleeding, anemia, sensory neuropathy such as paresthesia, dysesthesia, laryngospasm and facial muscle spasms,gastrointestinal disorders such as nausea, vomiting, stomatitis, flatulence, abdomen enlarged and Grade 4 intestinal obstruction, Grade 4 dehydration, dyspnea, wheezing, chest pain, respiratory failure, severe bradycardia and death.Patients suspected of receiving an overdose should be monitored, and supportive treatment should be administered.

Storage

Store at temperature not exceeding 25 °C in a dry place. Protect from light and moisture.

Packaging

Oxaliplat® 50: It is supplied in vial containing 50 mg of oxaliplatin USP as a sterile, preservative-free lyophilized powder for reconstitution and a vial containing 10 ml water for injection.
Oxaliplat® 100: It is supplied in vial containing 100 mg of oxaliplatin USP as a sterile, preservative-free lyophilized powder for reconstitution and a vial containing 20 ml water for injection.

Medicine: Keep out of reach of children

For further information, please contact: 01977 158 926
(9.00 am - 5.00 pm)

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