Abridged Prescribing Information

Mytrex™ (Pemetrexed)

Composition: MyTrex 500 mg & 100 mg vial contains Pemetrexed 500 mg & 100 mg as Pemetrexed disodium IP respectively. **Indication:** Pemetrexed in combination with Cisplatin is indicated for the treatment of chemotherapy-naive patients with unresectable malignant pleural mesothelioma. Pemetrexed in combination with Cisplatin is indicated as a first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. Pemetrexed is indicated as a monotherapy for the maintenance treatment of locally advanced or metastatic Non Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based therapy. **Dosage and administration:** Pemetrexed disodium combination use in NSCLC and mesothelioma: Recommended dose of MyTrex is 500 mg/m^2 IV on day 1 of each 21-day cycle in combination with Cisplatin 75 mg/m^2 IV beginning 30 minutes after MyTrex administration. Single-agent use in NSCLC: Recommended dose of MyTrex is 500 mg/m^2 IV on day 1 of each 21-day cycle. Dose Reductions: Dose reductions or discontinuation may be needed based on toxicities from the preceding cycle of therapy. **Special population:** Lactation: Breastfeeding should be discontinued during Pemetrexed therapy. Pediatric: No data available. Elderly patients: Patients 65 years of age or older are at increased risk of adverse events compared to patients younger than 65 years old. No dose reductions other than those recommended for all patients are necessary. Renal Insufficiency: Plasma clearance of pemetrexed decreases as renal function decreases. **Contraindications:** Pemetrexed is contraindicated in women of childbearing age unless adequate contraception is used and is also contraindicated in patients with known hypersensitivity to pemetrexed or to any of the excipients. **Warnings and precautions:** Premedication regimen: Instruct patients to take Folic acid and Vitamin B12. Pretreatment with Dexamethasone or equivalent reduces cutaneous reaction. Bone marrow suppression: Reduce doses for subsequent cycles based on hematologic and nonhematologic toxicities. Renal function: Do not administer when CrCl <45 mL/min. NSAIDs with renal insufficiency: Use caution in patients with mild-to-moderate renal insufficiency (CrCl 45–79 mL/min). Lab monitoring: Do not begin next cycle unless ANC ≥1500 cells/mm^3, platelets ≥100,000 cells/mm^3 and CrCl ≥45 mL/min. Pregnancy: Fetal harm can occur when administered to a pregnant woman. **Adverse reactions:** The most common adverse reactions (incidence ≥20%) with single-agent use are fatigue, nausea and anorexia. Additional common adverse reactions when used in combination with Cisplatin include vomiting, neutropenia, leukopenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation. **Over dosage and treatment:** There have been few cases of Pemetrexed overdose. Reported toxicities included neutropenia, anemia, thrombocytopenia, mucositis, and rash. Anticipated complications of overdose include bone marrow suppression as manifested by neutropenia, thrombocytopenia, and anemia. In addition, infection with or without fever, diarrhea and mucositis may be seen. If an overdose occurs, general supportive measures should be instituted as deemed necessary by the treating physician. **Storage:** MyTrex should be stored below 25°C, excursions permitted up to 30°C. Protect from light.

Dated: 1st August 2017

For more details and information, please refer the pack insert or full prescribing information