Abridged Prescribing Information

Stritoxol or MyTaxel™ (Paclitaxel Injection IP)

Composition: Paclitaxel Inj. IP is available as 30 mg/5ml, 100 mg/16.7 ml, and 260 mg/43.3ml multidose vial. **Indications:** a) Ovarian carcinoma: First-line therapy in combination with cisplatin for the treatment of advanced carcinoma of the ovary and subsequent therapy for the treatment of advanced carcinoma of the ovary. b) Breast carcinoma: Adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy, treatment of breast cancer after relapse within 6 months of adjuvant chemotherapy, treatment of locally advanced or metastatic breast cancer in combination with gemcitabine with relapsed disease following adjuvant/neoadjuvant chemotherapy, initial treatment of locally advanced or metastatic breast cancer in combination with an anthracycline, initial treatment of locally advanced or Metastatic Breast Cancer (MBC) in combination with trastuzumab, in patients who overexpress HER-2 at a 2+ or 3+ level. Treatment of breast cancer after failure of combination chemotherapy for metastatic disease C) Non-Small Cell Lung Carcinoma (NSCLC): First-line therapy in combination with a platinum compound, for the treatment of NSCLC in patients who are not candidates for potentially curative surgery and/or radiation therapy. D) Kaposi's Sarcoma: Second-line treatment of AIDS-related Kaposi's sarcoma. E) Gastric Carcinoma: Treatment of advanced gastric carcinoma. E) Carcinoma of Head and Neck: Treatment of advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN), newly diagnosed but unresectable locally advanced SCCHN, recurrent SCCHN, if surgery or radiation is not feasible, palliative treatment for metastatic SCCHN. **Dosage and Administration:** Paclitaxel should be administered through an in-line filter with a microporous membrane not greater than 0.22 microns. All patients must be premedicated prior to paclitaxel administration to reduce the risk of severe hypersensitivity reactions. A) Ovarian Carcinoma: Combination therapy: For treatment-naive patients, given every 3 weeks, IV paclitaxel is administered over 3 hours at a dose of 175 mg/m^2. Alternatively, a more myelosuppressive regimen of paclitaxel may also be administered IV at a dose of 135 mg/m^2 over 24 hours every 3 weeks. Single-agent therapy: In patients previously treated with chemotherapy, paclitaxel 175 mg/m^2 or 135 mg/m^2 is administered IV over 3 hours every 3 weeks. Breast Carcinoma: Adjuvant therapy: Paclitaxel 175 mg/m^2 IV over 3 hours every 3 weeks. Alternatively, paclitaxel administered 80 mg/m^2 IV over 1 hour every week for 12 courses. Single-agent, first-line therapy after relapse within 6 months of adjuvant chemotherapy: Paclitaxel 175 mg/m^2 administered IV over 3 hours every 3 weeks. Combination, first-line therapy of advanced or MBC: After relapse following adjuvant/neoadjuvant chemotherapy: In combination with gemcitabine, paclitaxel 175 mg/m^2 administered on day 1 over approximately 3 hours as an IV infusion. In combination with doxorubicin: Paclitaxel 220 mg/m^2 administered IV over a period of 3 hours with a 3-week interval between courses. In combination with trastuzumab: Paclitaxel 175 mg/m^2 administered IV over a period of 3 hours, with a 3-week interval between courses. Single agent, subsequent therapy after failure of combination chemotherapy for metastatic disease: Paclitaxel 175 mg/m^2 administered IV over 3 hours every 3 weeks. Weekly paclitaxel: Paclitaxel 80-100 mg/m^2 administered IV over 1 hour every 1 week. NSCLC: Combination therapy: Paclitaxel administered IV over 24 hours at a dose of 135 mg/m^2 followed by cisplatin 75 mg/m^2 every 3 weeks. AIDS-Related Kaposi's Sarcoma: Second-line therapy: Paclitaxel 135 mg/m^2 administered IV over 3 hours with a 3-week interval between courses or 100 mg/m^2 administered IV over 3 hours with a 2-week interval between courses. Gastric Carcinoma: Paclitaxel 210 mg/m^2 administered IV over 3 hours every 3 weeks when given as monotherapy. Carcinoma of Head and Neck: Paclitaxel 175 mg/m^2 administered IV over 3 hours every 3 weeks when given as monotherapy or combination chemotherapy. **Contraindications**: Paclitaxel is contraindicated in patients who have history of severe hypersensitivity reactions to paclitaxel or polyoxyethylated castor oil. Paclitaxel should not be administered to patients with solid tumors who have baseline neutrophil counts of <1500 cells/mm^3 or patients with AIDS-related Kaposi's sarcoma with baseline or subsequent

neutrophil counts of <1000 cells/mm^3. **Warnings and Precautions:** Paclitaxel should be administered as a diluted infusion. Pregnancy and Lactation: Paclitaxel may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant during therapy with paclitaxel. It is not known whether paclitaxel is excreted in human milk. Breast-feeding should be discontinued for the duration of paclitaxel therapy. Pediatric Use: The safety and effectiveness of paclitaxel in pediatric patients have not been established. Anaphylaxis and severe hypersensitivity: Reactions have occurred commonly in patients receiving paclitaxel. Hematologic Toxicity: Bone marrow suppression is dose and schedule dependent and is the principal dose-limiting toxicity within a regimen. Paclitaxel should not be administered to patients with baseline neutrophil counts of less than 1500 cells/mm^3. Cardiovascular Toxicity: Hypotension, hypertension and bradycardia have been observed during paclitaxel administration. Nervous System: The occurrence of peripheral neuropathy is frequent, but usually not severe. Hepatic Impairment: Patients with hepatic impairment may be at increased risk of toxicity, particularly grade III-IV myelosuppression. **Adverse reactions:** Paclitaxel + Cisplatin: Myelosuppression appeared to be less frequent. Incidence of severe neurotoxicity is more common at a paclitaxel dose of 175 mg/m^2 given by 3-hour infusion (21%) than at a dose of 135 mg/m^2 given by 24-hour infusion (3%). Increased risk of renal failure observed with the combination therapy of paclitaxel and cisplatin in gynecological cancers as compared to cisplatin alone. Paclitaxel + Trastuzumab: Heart failure, infection, chills, fever, cough, rash, arthralgia, tachycardia, diarrhea, hypertonia, epistaxis, acne, herpes simplex, accidental injury, insomnia, rhinitis, sinusitis, and injection-site reaction. Paclitaxel + Doxorubicin: Congestive heart failure has been reported and cases of myocardial infarction have been reported rarely. Cardiac dysfunction and reduction of left ventricular ejection fraction or ventricular failure have been reported typically in patients on paclitaxel who have received other chemotherapy, notably anthracycline. **Overdosage:** There is no known antidote for paclitaxel overdosage. The primary anticipated complications of overdosage would consist of bone marrow suppression, peripheral neurotoxicity and mucositis. Overdoses in pediatric patients may be associated with acute ethanol toxicity. **Special population**: Renal Impairment: The effect of renal impairment on the disposition of paclitaxel has not been investigated. **Storage:** Store at a temperature not exceeding 25°C. Protect from light. Do not freeze.

Dated: 06th Sep 2017

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