JEVTANA®

Cabazitaxel Injection for Intravenous Infusion

COMPOSITION

One single-use vial Jevtana 60 mg /1.5 mL concentrate contains 60 mg cabazitaxel (solvent free and anhydrous) in a total volume of 1.5 mL (Fill volume: 1.83mL per 73.2mg of Jevtana). Solvent vial contains 4.5mL (fill volume: 5.76mL) of ethanol 96% in Water for Injection.

THERAPEUTIC INDICATIONS

Jevtana in combination with prednisone is indicated for the treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen.

DOSAGE AND ADMINISTRATION

Jevtana should only be prepared and administered by personnel trained in handling cytotoxic agents. Refer to ENTIRE steps of preparation mentioned in the full prescribing information prior to administration.

Premedicate prior (at least 30 minutes before) to each administration with antihistamine, corticosteroid and H2 antagonist. Dilution process must be carried out in aseptic manner for preparing the solution for infusion using the supplied solvent. The recommended dose of Jevtana is 25 mg/m^2 administered as a 1-hour intravenous infusion every 3 weeks in combination with oral prednisone 10 mg administered daily throughout Jevtana treatment. Use an in-line filter of 0.22 micrometer nominal pore size (also referred to as 0.2 micrometer) during administration**. Special Populations:** ***Children:*** Safety and efficacy has not been established. ***Elderly Patients:*** No specific dose adjustment is recommended. ***Hepatic impairment:*** Patients with mild hepatic impairment (total bilirubin >1 to ≤1.5 x Upper Limit of Normal (ULN) or AST >1.5 x ULN), should have cabazitaxel dose reduced to 20 mg/m^2. Jevtana should not be given to patients with severe hepatic impairment [total bilirubin >3 x ULN. ***Renal impairment:*** No dose adjustment is necessary in mild renal impairment not requiring hemodialysis. Patients presenting end-stage renal disease should be treated with caution and monitored carefully during treatment. **Concomitant drug use:** Concomitant drugs that are strong CYP3A inducers or strong CYP3A inhibitors should be avoided.

SAFETY-RELATED INFORMATION

Contraindications: In patients with a history of severe hypersensitivity reactions to cabazitaxel or other drugs formulated with polysorbate 80; neutrophil counts less than 1,500/mm^3; severe hepatic impairment.

Warnings and Precautions: Bone marrow suppression manifested as neutropenia, anemia, thrombocytopenia, or pancytopenia may occur. Primary prophylaxis with G-CSF should be considered in patients with high-risk clinical features (age > 65 years, poor performance status, previous episodes of febrile neutropenia, extensive prior radiation ports, poor nutritional status, or other serious comorbidities) that predispose them to increased complications from prolonged neutropenia. Neutropenia is the most common adverse reaction. Monitoring of complete blood count is essential on a weekly basis during cycle 1 and before each treatment cycle thereafter so that the dose can be adjusted, if needed. Patients should be observed closely for hypersensitivity reactions especially during the first and second infusions and the ones who have a history of severe hypersensitivity reactions should not be rechallenged with Jevtana. If patients experience diarrhea following administration of Jevtana they should be treated with commonly used anti-diarrheal medications. Appropriate measures should be taken to rehydrate the patients. Gastrointestinal (GI) hemorrhage and perforation, ileus, colitis, including fatal outcome, have been reported in patients treated with cabazitaxel. Caution advised with treatment of patients most at risk of developing GI complications. Hemoglobin and hematocrit should be checked before treatment with cabazitaxel and if patients exhibit signs or symptoms of anemia or blood loss. Caution is recommended in patients with hemoglobin <10 g/dl and appropriate measures should be taken as clinically indicated. Renal disorders, have been reported in association with sepsis, severe dehydration due to diarrhea, vomiting and obstructive uropathy. Appropriate measures should be taken to identify the cause and intensively treat the patients if this occurs and renal function should be monitored. Urinary disorders : Cystitis due to radiation recall phenomenon has been reported with cabazitaxel therapy in patients who have previously received pelvic radiation therapy and docetaxel containing regimen. Interruption or discontinuation of cabazitaxel therapy may be necessary.

Interstitial pneumonia/pneumonitis, interstitial lung disease and acute respiratory distress syndrome have been reported and may be associated with fatal outcome. If new or worsening pulmonary symptoms develop, patients should be closely monitored, promptly investigated, and appropriately treated. Interruption of cabazitaxel therapy is recommended until diagnosis is available.Cardiac arrhythmias have been reported, most commonly tachycardia and atrial fibrillation. Elderly patients (≥65 years of age) may be more likely to experience certain adverse reactions including neutropenia or febrile neutropenia. Jevtana is contraindicated in patients with severe hepatic impairment (total bilirubin > 3 x ULN). Dose should be reduced for patients with mild (total bilirubin >1 to ≤1.5 x ULN or AST >1.5 x ULN) hepatic impairment.

Pregnancy: There are no data from the use of cabazitaxel in pregnant women. Cabazitaxel has been shown to be genotoxic by an aneugenic mechanism. In non-clinical studies in rats and rabbits, cabazitaxel has also been shown to be embryotoxic, fetotoxic, and abortifacient at exposures significantly lower than those expected at the recommended human dose level. Cabazitaxel crosses the placenta barrier. Jevtana is not recommended during pregnancy.

Lactation: Should not be used during breast-feeding.

Adverse Reactions: Very common adverse reactions: Anemia, leukopenia, neutropenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy (including peripheral sensory and motor neuropathy), pyrexia, dyspnea, dysguesia, cough, arthralgia, and alopecia. Common adverse reactions: neutropenia, leukopenia, anemia, febrile neutropenia, diarrhea, fatigue, and asthenia. Post Marketing Experiences: Renal and urinary disorders, Cystitis due to radiation recall phenomenon was reported uncommonly

For full prescribing information please write to: Sanofi Healthcare India Private Limited, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai- 400072.

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