Abridged Prescribing Information

Myzotem™ (Temozolomide)

Composition: Myzotem capsule contains 5 mg, 20 mg, 100 mg, or 250 mg Temozolomide (TMZ) capsules. **Indication**: Myzotem is indicated for the treatment of adult patients with newly-diagnosed Glioblastoma multiforme (GBM) concomitantly with radiotherapy and subsequently as monotherapy treatment. Children from the age of 3years, adolescents and adult patients with malignant glioma, such as GBM or anaplastic astrocytoma, showing recurrence or progression after standard therapy. **Dosage and Administration:** Adult patients with newly-diagnosed GBM: Temozolomide capsule is administered in combination with focal radiotherapy (concomitant phase) followed by up to 6 cycles of TMZ monotherapy (monotherapy phase). Concomitant phase: TMZ is administered orally at a dose of 75 mg/m^2 daily for 42 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions). No dose reductions are recommended, but delay or discontinuation of TMZ administration should be decided weekly according to hematological and non-hematological toxicity. Administration: Temozolomide hard capsules should be administered in the fasting state. The capsules must be swallowed whole with a glass of water and must not be opened or chewed. If vomiting occurs after the dose is administered, a second dose should not be administered that day. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Hypersensitivity to Dacarbazine (DTIC) and severe myelosuppression. **Warnings and Precautions:** Opportunistic infections and reactivation of infections: Opportunistic infections such as Pneumocystis jiroveci pneumonia (PCP) and reactivation of infections such as Hepatitis B virus, Cytomegalovirus (HBV, CMV) have been observed during the treatment with TMZ. Pneumocystis jiroveci pneumonia: Patients who receive concomitant TMZ and RT for prolonged 42-day schedule are shown to be at particular risk of developing PCP. Thus, prophylaxis against PCP is required. If lymphopenia occurs, they are to continue the prophylaxis until recovery of lymphopenia to grade ≤1. All patients receiving TMZ, particularly patients receiving steroids, should be observed closely for the development of PCP, regardless of the regimen. Cases of fatal respiratory failure have been reported in patients using TMZ, in particular in combination with Dexamethasone or other steroids. Hepatotoxicity: Hepatic injury, including fatal hepatic failure, has been reported. **Adverse Reactions:** Nausea, vomiting, constipation, anorexia, headache and fatigue. Convulsions were reported very commonly in the newly-diagnosed GBM patients receiving monotherapy, and rash were reported very commonly in newly-diagnosed GBM patients receiving TMZ concurrent with RT and also as monotherapy, and commonly in recurrent glioma. Most hematologic adverse reactions were reported commonly or very commonly in both indications. **Overdosage and Treatment:** Doses of 500, 750, 1,000, and 1,250 mg/m^2 have been evaluated clinically in patients. Dose-limiting toxicity was hematological and was reported with any dose but is expected to be more severe at higher doses. There are reports of patients who have taken the recommended dose for more than 5 days of treatment (up to 64 days) with adverse events reported including bone marrow suppression, with or without infection, in some cases severe and prolonged and resulting in death. In the event of an overdose, hematological evaluation is needed. Supportive measures should be provided as necessary. **Storage**: Store in a cool, dry place. Protect from light. Keep the bottle tightly closed in order to protect from moisture.

Dated: 30th September 2017

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