Pantone Metallic Coated 8483 C & 185 C

W- 180 mm X, H- 220 mm

TMZ™
Temozolomide USP

Jenphar
Bangladesh
جنفار
بنغلاديش

Composition:

TMZ™ 100: Each capsule contains Temozolomide USP 100 mg.

Pharmacology:

Temozolomide, a triazene, is an inactive prodrug. It is chemically hydrolysed to 3-methyl-(triazen-1-yl) imidazole-4-carboxamide (MTIC), the active metabolite of dacarbazine. The cytotoxicity of MTIC is believed to be due alkylation of DNA, mainly at the O^6 and N^7 positions of guanine.

Indication:

Newly Diagnosed Glioblastoma Multiforme: Temozolomide is indicated for the treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.

Refractory Anaplastic Astrocytoma: Temozolomide is indicated for the treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

Dose & administration:

Newly diagnosed glioblastoma multiforme: 75 mg/m² for 42 days concomitant with focal radiotherapy followed by initial maintenance dose of 150 mg/m² once daily for Days 1-5 of a 28-day cycle of Temozolomide for 6 cycles

Refractory Anaplastic Astrocytoma: Initial dose 150 mg/m² once daily for 5 consecutive days per 28-day treatment cycle. The recommended dose for Temozolomide as an intravenous infusion over 90 minutes is the same as the dose for the oral capsule formulation. Bioequivalence has been established only when temozolomide for injection was given over 90 minutes.

Contra-indication:

Temozolomide is contraindicated in patients who have a history of hypersensitivity reaction to any of its components.

Warning and precaution:

Severe hepatic and renal impairment: Elderly >70 yr, children.

Women of child bearing potential should avoid becoming pregnant during therapy. Males should be advised not to father a child up to 6 month after treatment and to consider cryoconservation of sperms due to possibility of irreversible infertility. Unknown if distributed into breastmilk, discontinue nursing due to potential risk. May impair ability to drive or operate machinery. Swallow capsule whole with a full glass of water on an empty stomach or at bedtime. Do not take a 2nd dose if capsules are vomited. Monitor CBC weekly during concomitant therapy and on day 22 of each 28 day treatment cycle, followed by weekly blood count until recovery. Hepatitis screening and prophylactic therapy with antiviral agents as clinically indicated to be considered. Prophylaxis for Pneumocystis jiroveci (or Pneumocystis carinii) pneumonia (PCP) needed for all patients receiving concomitant temozolomide and radiation therapy for the 42-day regimen; If patients experience lymphocytopenia during the concomitant phase of therapy, PCP prophylaxis should be continued until recovery from lymphocytopenia. Monitor closely for PCP development in all patients. Anti-emetic prophylaxis recommended.

Side Effects:

The most common adverse reactions (>_10% incidence) are: alopecia, fatigue, nausea, vomiting, headache, constipation, anorexia, convulsions, rash, hemiparesis, diarrhea, asthenia, fever, dizziness, coordination abnormal, viral infection, amnesia, and insomnia. The most common Grade 3 to 4 hematologic laboratory abnormalities (>_ 10% incidence) that have developed during treatment with temozolomide are: lymphopenia, thrombocytopenia, neutropenia and leukopenia. Allergic reactions have also been reported.

Use in Specific Populations:

Pregnancy: Category D.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants and tumorigenicity shown for temozolomide in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of temozolomide to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies of temozolomide did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment: Caution should be exercised when temozolomide is administered to patients with severe renal impairment

Hepatic Impairment: Caution should be exercised when temozolomide is administered to patients with severe hepatic impairment

Drug Interaction:

Valproic Acid: Administration of valproic acid decreases oral clearance of temozolomide by about 5%.The clinical implication of this effect is not known.

Overdose:

Doses of 500, 750, 1000 and 1250 mg/m^2 (total dose per cycle over 5 days) have been evaluated clinically in patients. Dose-limiting toxicity was hematologic and was reported with any dose but is expected to be more severe at higher doses. An overdose of 2000 mg per day for 5 days was taken by one patient and the adverse reactions reported were pancytopenia, pyrexia, multi-organ failure and death. There are reports of patients who have taken more than 5 days of treatment (up to 64 days), with adverse reactions reported including bone marrow suppression, which in some cases was severe and prolonged, and infections which resulted in death. In the event of an overdose, hematologic evaluation is needed. Supportive measures should be provided as necessary.

Storage:

Keep in a cool and dry place at (15°-30°)C, protect from light. Keep out of the reach of children.

Packing:

TMZ™ 100 : Each box contains 1X5's capsules in Alu-Alu blister pack.

Manufactured for
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.
by **Techno Drugs Ltd.**
Satirpara, Narsingdi, Bangladesh

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