TEMOTOR

To be sold by retail on the prescription of Oncologist only

Abbreviated Prescribing information for Temotor (Temozolomide capsules I.P. 20/100/250 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Temozolomide (TMZ) is Antineoplastic agents. **INDICATION:** Patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment. Also indicated for the children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy. **DOSAGE AND ADMINISTRATION:** *Adult and paediatric patients 3 years of age or older with recurrent or progressive malignant glioma*: Patients previously untreated with chemotherapy: oral dose of 200 mg/m^2 once daily for the first 5 days followed by a 23 day treatment interruption (total of 28 days). Patients previously treated with chemotherapy: initial dose is 150 mg/m^2 once daily, to be increased in the second cycle to 200 mg/m^2 once daily, for 5 days if there is no haematological toxicity. *Concomitant phase*: oral dose of 75 mg/m^2 daily for 42 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions). *Monotherapy phase:* Dose in Cycle 1 (monotherapy) is 150 mg/m^2 once daily for 5 days followed by 23 days without treatment. At the start of Cycle 2, the dose is escalated to 200 mg/m^2 if the CTC non-haematological toxicity for Cycle 1 is Grade ≤ 2 (except for alopecia, nausea and vomiting), absolute neutrophil count (ANC) is $\geq 1.5 \times 10^9/l$, and the thrombocyte count is $\geq 100 \times 10^9/l$. **CONTRINDICATIONS:** Hypersensitivity to the active substance, dacarbazine (DTIC) or to any of the excipients. Severe myelosuppression. **WARNINGS & PRECAUTIONS:** *Pneumocystis jirovecii* pneumonia, hepatotoxicity (hepatic injury, including fatal hepatic failure), myelodysplastic syndrome and secondary malignancies, including myeloid leukaemia, nausea and vomiting, Adult patients with newly-diagnosed glioblastoma multiforme: Anti-emetic prophylaxis is recommended prior to the initial dose of concomitant phase, Patients who have experienced severe (Grade 3 or 4) vomiting in previous treatment cycles may require anti-emetic therapy. Men being treated with TMZ should be advised not to father a child up to 6 months after receiving the last dose. **DRUG INTERACTIONS:** Interacts with valproic acid and myelosuppressive agents. **ADVERSE REACTIONS:** nausea, vomiting, constipation, anorexia, headache, fatigue, convulsions, infection, herpes simplex, wound infection, pharyngitis, candidiasis oral, neutropenia, thrombocytopenia, lymphopenia, leukopenia, febrile neutropenia, anaemia, cushingoid, anorexia, hyperglycaemia, weight decreased, hypokalemia, alkaline phosphatase increased, weight increased, anxiety, emotional lability, insomnia, agitation, apathy, behaviour disorder, depression, hallucination, headache, convulsions, consciousness decreased, somnolence, aphasia, balance impaired, dizziness, confusion, memory impairment, concentration impaired, neuropathy, paresthesia, speech disorder, tremor, vision blurred, hemianopia, visual acuity reduced, vision disorder, visual field defect, eye pain, hearing impairment, otitis media, tinnitus, hyperacusis, ear ache, palpitation, haemorrhage, oedema, oedema leg, cerebral haemorrhage, hypertension, dyspnoea, coughing, pneumonia, upper respiratory infection, nasal congestion, stomatitis, diarrhoea, abdominal pain, dyspepsia, dysphagia, rash, alopecia, dermatitis, dry skin, erythema, pruritus, skin exfoliation, photosensitivity reaction, pigmentation abnormal, muscle weakness, arthralgia, myopathy, back pain, musculoskeletal pain, myalgia, micturition frequency, urinary incontinence, impotence, vaginal haemorrhage, menorrhagia, amenorrhea, vaginitis, breast pain, toxic epidermal necrolysis, Stevens-Johnson syndrome, hyperbilirubinemia, cholestasis, hepatitis, hepatic injury and hepatic failure.

MARKETED BY:

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(Additional information is available on request)