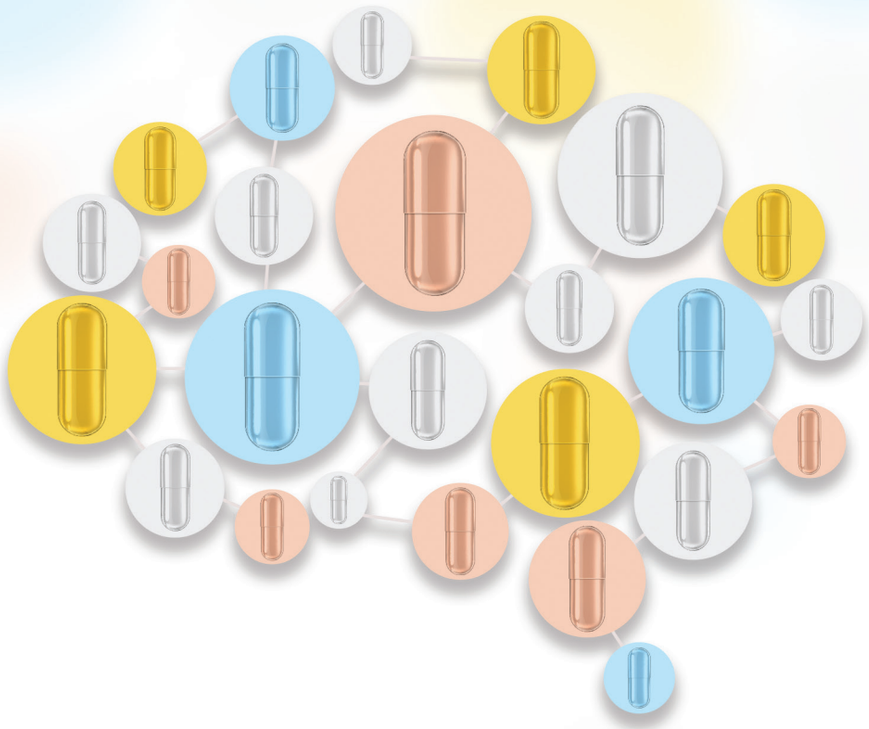
Sobhan Oncology
Keeping Hope Alive



HEALTH, HAPPINESS & HOPE

ALL IN A HARD CAPSULE

Preferred 1st line & 2nd line in Malignant glioma

Radotem®

Temozolomide 20,100,140, 250 mg

Radotem®

Temozolomide 20,100,140, 250 mg

INDICATIONS AND USAGE

Temozolomide is an alkylating drug indicated for the treatment of adult patients with:

- Newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment.
- Refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

DOSAGE AND ADMINISTRATION

- Administer orally.
- Newly Diagnosed Glioblastoma:

75 mg/m^2 once daily for 42 days concomitant with focal radiotherapy followed by initial maintenance dose of 150 mg/m^2 once daily for Days 1 to 5 of each 28-day cycle for 6 cycles. May increase maintenance dose to 200 mg/m^2 for cycles 2 – 6 based on toxicity.

- Provide Pneumocystis pneumonia (PCP) prophylaxis during concomitant phase and continue in patients who develop lymphopenia until resolution to grade 1 or less.

• Refractory Anaplastic Astrocytoma: Initial dose of 150 mg/m^2 once daily on Days 1 to 5 of each 28-day cycle.

DOSAGE FORMS AND STRENGTHS

- Capsules: 20 mg, 100 mg, 140 mg, and 250 mg

CONTRAINDICATIONS

- History of hypersensitivity to temozolomide or any other ingredients in temozolomide and dacarbazine.

WARNINGS AND PRECAUTIONS

- Myelosuppression: Monitor absolute neutrophil count (ANC) and platelet count prior to each cycle and during treatment. Geriatric patients and women have a higher risk of developing myelosuppression.
- **Myelodysplastic Syndrome and Secondary Malignancies**, including myeloid leukemia, have been observed.
- **Pneumocystis Pneumonia (PCP):** Closely monitor all patients, particularly those receiving steroids, for the development of lymphopenia and PCP.
- **Hepatotoxicity:** Fatal and severe hepatotoxicity have been reported. Perform liver tests at baseline, midway through the first cycle, prior to each subsequent cycle, and approximately 2 to 4 weeks after the last dose of temozolomide.
- **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. Advise male patients with pregnant partners or female partners of reproductive potential to use condoms.

ADVERSE REACTIONS

- The most common adverse reactions (≥20% incidence) are: alopecia, fatigue, nausea, vomiting, headache, constipation, anorexia, and convulsions.
- The most common Grade 3 to 4 hematologic laboratory abnormalities (≥10% incidence) in patients with anaplastic astrocytoma are: decreased lymphocytes, decreased platelets, decreased neutrophils, and decreased leukocytes.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed during treatment with temozolomide and for at least 1 week after the final dose.

Contraception

Females: temozolomide can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with temozolomide and for at least 6 months after the last dose.

Males: Because of the potential for embryofetal toxicity and genotoxic effects on sperm cells, advise male patients with pregnant partners or female partners of reproductive potential to use condoms during treatment with temozolomide and for at least 3 months after the final dose. Advise male patients not to donate semen during treatment with temozolomide and for at least 3 months after the final dose. Infertility temozolomide may impair male fertility.

Pediatric use: Safety and effectiveness of temozolomide have not been established in pediatric patients.

Geriatric Use: In the Newly Diagnosed Glioblastoma trial, Study MK-7365-051, 15% of patients were 65 years and older. This study did not include sufficient numbers of patients aged 65 years and older to determine differences in effectiveness from younger patients. No overall differences in safety were observed between patients ≥65 years and younger patients.

Renal Impairment: No dosage adjustment is recommended for patients with creatinine clearance (CLcr) of 36 to 130 mL/min/m^2. The recommended dose of temozolomide has not been established for patients with severe renal impairment (CLcr < 36 mL/min/m^2) or for patients with end-stage renal disease on dialysis.

Hepatic Impairment: No dosage adjustment is recommended for patients with mild to moderate hepatic impairment. The recommended dose of temozolomide has not been established for patients with severe hepatic impairment.

OVERDOSAGE: Dose-limiting toxicity was myelosuppression and was reported with any dose but is expected to be more severe at higher doses.

HEALTH, HAPPINESS & HOPE

ALL IN A HARD CAPSULE

www.sobhanoncology.com

+9821-83878