

TEMODAR® (temozolomide) for injection

PHARMACIST:

Dispense enclosed Patient Package Insert to each patient.

PHARMACIST INFORMATION SHEET

What is TEMODAR? *[See Full Prescribing Information, Indications and Usage (1).]*

TEMODAR® (temozolomide) is an alkylating drug for the treatment of adult patients with newly diagnosed glioblastoma multiforme and refractory anaplastic astrocytoma.

How is TEMODAR dosed? *[See Full Prescribing Information, Recommended Dosage and Dosage Modifications for Newly Diagnosed Glioblastoma (2.1), Recommended Dosage and Dosage Modifications for Refractory Anaplastic Astrocytoma (2.2).]*

The physician calculates the daily dose of TEMODAR for a given patient based on the patient's body surface area (BSA). The recommended dose for TEMODAR as an intravenous infusion over 90 minutes is the same as the dose for the oral capsule formulation. Adjust the dose for subsequent cycles according to nadir neutrophil and platelet counts in the previous cycle and at the time of initiating the next cycle.

Dosing for Patients with Refractory Anaplastic Astrocytoma *[See Full Prescribing Information, Recommended Dosage and Dosage Modifications for Refractory Anaplastic Astrocytoma (2.2).]*

The initial dose is 150 mg/m² intravenously once daily for 5 consecutive days per 28-day treatment cycle. Increase the TEMODAR dose to 200 mg/m²/day for 5 consecutive days per 28-day treatment cycle if both the nadir and day of dosing (Day 29, Day 1 of next cycle) absolute neutrophil counts (ANC) are greater than or equal to 1.5 x 10⁹/L (1500/μL) and both the nadir and Day 29, Day 1 of next cycle platelet counts are greater than or equal to 100 x 10⁹/L (100,000/μL). During treatment, obtain a complete blood count on Day 22 (21 days after the first dose), and weekly until the ANC is above 1.5 x 10⁹/L (1500/μL) and the platelet count exceeds 100 x 10⁹/L (100,000/μL). Do not start the next cycle of TEMODAR until the ANC and platelet count exceed these levels. If the ANC falls to less than 1.0 x 10⁹/L (1000/μL) or the platelet count is less than 50 x 10⁹/L (50,000/μL) during any cycle, reduce the dose for the next cycle by 50 mg/m². Permanently discontinue TEMODAR in patients who are unable to tolerate a dose of 100 mg/m² per day.

Patients should continue to receive TEMODAR until their physician determines that their disease has progressed, or until unacceptable side effects or toxicities occur. In the clinical trial, treatment could be continued for a maximum of 2 years, but the optimum duration of therapy is not known. Physicians may alter the treatment regimen for a given patient.

Dosing for Patients with Newly Diagnosed Glioblastoma Multiforme *[See Full Prescribing Information, Recommended Dosage and Dosage Modifications for Newly Diagnosed Glioblastoma (2.1).]*

Concomitant Phase Treatment Schedule

Administer TEMODAR at 75 mg/m² daily for 42 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions), followed by maintenance TEMODAR for 6 cycles. No dose reductions are recommended; however, dose interruptions may occur based on patient tolerance. Continue the TEMODAR dose throughout the 42-day concomitant period up to 49 days if all of the following conditions are met: absolute neutrophil count greater than or equal to 1.5 x 10⁹/L, platelet count greater than or equal to 100 x 10⁹/L, and nonhematological adverse reactions less than or equal to Grade 1 (except for alopecia, nausea, and vomiting). During treatment, obtain a complete blood count weekly. Interrupt or discontinue temozolomide dosing during the concomitant phase according to the hematological and nonhematological toxicity criteria [see *Table 1 in the Full Prescribing Information, Recommended Dosage and Dosage Modifications for Newly Diagnosed Glioblastoma (2.1)*]. *Pneumocystis pneumonia* (PCP) prophylaxis is required during the concomitant administration of TEMODAR and radiotherapy, and should be continued in patients who develop lymphocytopenia until resolution to Grade 1 or less.

Maintenance Phase Treatment Schedule

Four weeks after completing the TEMODAR and radiotherapy phase, administer TEMODAR for an additional 6 cycles of maintenance treatment. Dosage in Cycle 1 (maintenance) is 150 mg/m² once daily for 5 days followed by 23 days without treatment. At the start of Cycle 2, escalate the dose to 200 mg/m², if the nonhematologic adverse reactions for Cycle 1 are Grade less than or equal to 2 (except for alopecia, nausea, and vomiting), absolute neutrophil count (ANC) is greater than or equal to 1.5 x 10⁹/L, and the platelet count is greater than or equal to 100 x 10⁹/L. If the dose was not escalated at Cycle 2, do not escalate the dose in subsequent cycles. Maintain the dose at 200 mg/m² per day for the first 5 days of each subsequent cycle except if toxicity occurs.

During treatment, obtain a complete blood count on Day 22 (21 days after the first dose) and weekly until the ANC is above 1.5 x 10⁹/L (1500/μL) and the platelet count exceeds 100 x 10⁹/L (100,000/μL). Do not start the next cycle of TEMODAR until the ANC and platelet count exceed these levels. Base dose reductions during the next cycle on the lowest blood counts and worst nonhematologic adverse reactions during the previous cycle. Apply dose reductions or discontinuations during the maintenance phase [see *Table 2 in the Full Prescribing Information, Recommended Dosage and Dosage Modifications for Newly Diagnosed Glioblastoma (2.1)*].

How is TEMODAR for injection prepared? [See *Full Prescribing Information, Preparation and Administration, TEMODAR for injection (2.3)*.]

Take care in the handling and preparation of TEMODAR. Do not open vials. If vials are accidentally opened or damaged, take rigorous precautions with the contents to avoid inhalation or contact with the skin or mucous membranes. In case of powder contact, wash hands. Use gloves and safety glasses to avoid exposure in case of breakage of the vial. Consider implementing procedures for proper handling and disposal of

anticancer drugs {see “OSHA Hazardous Drugs.” reference below}. Several guidelines on this subject have been published.

1. Store TEMODAR for injection vials refrigerated at 2° - 8°C (36° - 46°F).
2. Bring the vial to room temperature prior to reconstitution with Sterile Water for Injection.
3. Using aseptic technique, reconstitute each vial with 41 mL Sterile Water for Injection. The resulting solution will contain 2.5 mg/mL temozolomide.
4. Gently swirl vial. Do not shake.
5. Visually inspect reconstituted solution, and discard if particulate matter or discoloration is observed.
6. Do not further dilute the reconstituted solution.
7. Store reconstituted solution at room temperature for up to 14 hours, including infusion time.
8. Using aseptic technique, withdraw up to 40 mL from each vial to make up the total dose and transfer into an empty 250 mL infusion bag. Discard any unused portion.
9. Attach the pump tubing to the bag, purge the tubing, and then cap.

How is TEMODAR for injection administered? *[See Full Prescribing Information, Preparation and Administration, TEMODAR for injection (2.3).]*

Administer TEMODAR for injection as an intravenous infusion over 90 minutes. Administer TEMODAR for injection only by intravenous infusion. Flush the lines before and after each TEMODAR infusion.

TEMODAR for injection may be administered in the same intravenous line with 0.9% Sodium Chloride injection only.

Because no data are available on the compatibility of TEMODAR for injection with other intravenous substances or additives, other medications should not be infused simultaneously through the same intravenous line.

What should the patient avoid during treatment with TEMODAR? *[See Full Prescribing Information, Use in Specific Populations, Pregnancy (8.1), Lactation (8.2), Females and Males of Reproductive Potential (8.3).]*

There are no dietary restrictions for patients taking TEMODAR. TEMODAR may affect testicular function and may cause birth defects. Advise male patients to exercise adequate birth control measures. Advise female patients to avoid becoming pregnant while receiving this drug. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 6 months after the last dose. Advise males of reproductive potential to use condoms during treatment and for at least 3 months after the last dose. Advise male patients not to donate semen during treatment with TEMODAR and for at least 3 months after the final dose. It is not known whether TEMODAR is excreted into breast milk. Because of the potential for serious adverse reactions in breastfed children, advise

women not to breastfeed while taking TEMODAR and for at least 1 week after the last dose.

What are the side effects of TEMODAR? [See Full Prescribing Information, Adverse Reactions (6).]

Alopecia, fatigue, nausea, and vomiting are the most common side effects associated with TEMODAR. Noncumulative myelosuppression is the dose-limiting toxicity. Patients should be evaluated periodically by their physician to monitor blood counts.

Other commonly reported side effects reported by patients taking TEMODAR are headache, constipation, anorexia, convulsions, bruising, petechia, and hematoma, as well as pain, irritation, itching, warmth, swelling, and erythema at the site of infusion.

How is TEMODAR supplied? [See Full Prescribing Information, How Supplied/Storage and Handling (16).]

TEMODAR for injection is supplied in single-dose glass vials containing 100 mg temozolomide (NDC 0085-1381-01). TEMODAR is also available as capsules in 5-mg, 20-mg, 100-mg, 140-mg, 180-mg, and 250-mg strengths.

References:

“OSHA Hazardous Drugs.” OSHA. <http://www.osha.gov/SLTC/hazardousdrugs/index>.

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