

Temozolomide

(te moe zoe' loe mide)

Brand Name(s): Temodar®

WHY is this medicine prescribed?

Temozolomide is used to treat certain types of brain tumors. Temozolomide is in a class of medications called alkylating agents. It works by slowing or stopping the growth of cancer cells in your body.

HOW should this medicine be used?

Temozolomide comes as a capsule to take by mouth. It is usually taken once a day in the evening at bedtime. Take temozolomide capsules on an empty stomach with a glass of water. Take temozolomide at around the same time every day. For some types of brain tumors, temozolomide is taken daily for 42–49 days. Then, after a 28-day break, it may be taken once a day for 5 days in a row, followed by a 23-day break before repeating the next dosage cycle. For treatment of other types of brain tumors, temozolomide is taken once a day for 5 days in a row, followed by a 23-day break before repeating the next dosage cycle. Your doctor will decide how many times you should repeat the treatment cycles. The length of treatment depends on the how well your body responds to it and the type of cancer that you have. Take temozolomide exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your full dose may contain more than one type and color of capsules and may be contained in more than one prescription bottle. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand.

Temozolomide capsules come in several different strengths. Your doctor may want you to take a combination of capsules to make up your full dose. Be sure that you know what each type of capsule looks like and how many you are to take of each. Ask your doctor or pharmacist if you have any questions.

If any of the capsules are broken or leaking, do not touch them with your bare hands and be careful not to breathe in the powder from the capsules. You should

wear rubber or latex gloves when you handle broken or opened capsules so that your skin does not come into contact with the powder. If the capsule contents do touch your skin, wash the area well with water right away.

Swallow the capsules whole; do not empty, chew, or crush them.

You may vomit after you take the medication. If this happens, let your doctor know right away. Do not take another dose of temozolomide on the same day.

Your doctor may need to delay your treatment or adjust your dose of temozolomide depending on your response to treatment and any side effects that you experience. Talk to your doctor about how you are feeling during your treatment. Do not stop taking temozolomide without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Are there OTHER USES for this medicine?

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What SPECIAL PRECAUTIONS should I follow?

Before taking temozolomide,

- tell your doctor and pharmacist if you are allergic to temozolomide, dacarbazine (DTIC-Dome) any other medications, or any of the ingredients in temozolomide capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: carbamazepine (Carbatrol, Eptol, Tegretol); co-trimoxazole (Bactrim, Septra); phenytoin (Dilantin, Phenytek); steroids such as dexamethasone (Decadron, Dexone),

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methylprednisolone (Medrol), and prednisone (Deltasone); and valproic acid (Stavzor, Depakene).

- tell your doctor if you have or have ever had kidney or liver disease.
- you should know that temozolomide may interfere with sperm production in men. However, you should not assume that you cannot get someone else pregnant. Tell your doctor if you are pregnant or plan to become pregnant, or if you plan to father a child. You or your partner should not become pregnant while you are taking temozolomide. Use a reliable method of birth control to prevent pregnancy. If you become pregnant while taking temozolomide, call your doctor. Temozolomide may harm the fetus.
- tell your doctor if you are breast-feeding. You should not breastfeed while you are taking temozolomide.

What SPECIAL DIETARY instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do IF I FORGET to take a dose?

Talk to your doctor about what to do if you miss a dose of temozolomide. Do not take a double dose to make up for a missed one.

What SIDE EFFECTS can this medicine cause?

Temozolomide may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- constipation
- loss of appetite
- sores in the mouth and throat
- headache
- pale skin
- lack of energy
- loss of balance or coordination
- fainting
- dizziness
- hair loss
- insomnia
- memory problems
- changes in vision

Some side effects can be serious. If you experience any of these symptoms, stop taking temozolomide and call your doctor immediately or get emergency medical treatment:

- unusual bleeding or bruising
- red or black, tarry stools
- pink, red, or dark brown urine
- coughing up or vomiting blood or material that looks like coffee grounds
- fever, sore throat, ongoing cough and congestion, or other signs of infection
- unusual tiredness or weakness
- rash
- unable to move one side of the body
- shortness of breath
- seizures
- yellowing of the skin or eyes
- pain in the upper right part of the stomach
- decreased urination

Temozolomide may increase the risk that you will develop other cancers. Talk to your doctor about the risks of taking temozolomide.

Temozolomide may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

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If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

What should I know about STORAGE and DISPOSAL of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p>) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org>

What should I do in case of OVERDOSE?

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help>. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- unusual bleeding or bruising

- red or black, tarry stools
- pink, red, or dark brown urine
- coughing up or vomiting blood or material that looks like coffee grounds
- fever, sore throat, ongoing cough and congestion, or other signs of infection

What OTHER INFORMATION should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order laboratory tests before, during, and after your treatment to check your body's response to temozolomide and to see if your blood cells are affected by this drug.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

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