



**PHARMACIST: Dispense with Patient Information Sheet available at <https://www.sunpharma.com/usa/products> to each patient.**

## Patient Information Temozolomide (TEM-oh-ZOE-loe-mide) Capsules, USP

### What are temozolomide capsules?

Temozolomide capsules are a prescription medicine used to treat adults with certain brain cancer tumors.

It is not known if temozolomide capsules are safe and effective in children.

### Do not take temozolomide capsules if you:

- have had an allergic reaction to temozolomide or any of the other ingredients in temozolomide capsules. See the end of this leaflet for a list of ingredients in temozolomide capsules. Symptoms of an allergic reaction with temozolomide capsules may include: a red itchy rash, or a severe allergic reaction, such as trouble breathing, swelling of the face, throat, or tongue, or severe skin reaction. If you are not sure, ask your healthcare provider.
- have had an allergic reaction to dacarbazine (DTIC), another cancer medicine.

### Before taking or receiving temozolomide capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant.

### Temozolomide capsule can harm your unborn baby and cause birth defects.

#### Females who can become pregnant:

- You should not become pregnant during treatment with temozolomide capsules.
- You should use an effective form of birth control (contraception) during treatment and for 6 months after your last dose of temozolomide capsules.
- Your healthcare provider should do a pregnancy test to make sure that you are not pregnant before you start taking temozolomide capsules.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with temozolomide capsules.

#### Males with a female partner who is pregnant or who can become pregnant:

- Use a condom for birth control (contraception) during treatment and for 3 months after taking your last dose of temozolomide capsules.
- **Do not** donate semen during treatment and for 3 months after your last dose of temozolomide capsules.
- are breastfeeding or plan to breastfeed. It is not known if temozolomide passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of temozolomide capsules.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

### How should I take temozolomide capsules?

- you may take temozolomide by mouth as a capsule.

Your healthcare provider will decide the best way for you to take temozolomide capsules.

- If your healthcare provider prescribes temozolomide capsules for you, take the capsules exactly as prescribed.

There are 2 common dosing schedules for taking or receiving temozolomide capsules depending on the type of brain cancer tumor that you have.

- People with certain brain cancer tumors take or receive temozolomide capsules:
  - 1 time each day for 42 to 49 days in a row, along with receiving radiation treatment. This is 1 cycle of treatment. After this, your healthcare provider may prescribe 6 more cycles of temozolomide as “maintenance” treatment. For each of these cycles, you take or receive temozolomide 1 time each day for 5 days in a row and then you stop taking it for the next 23 days. **This is a 28-day maintenance treatment cycle.**
- People with certain other brain cancer tumors take or receive temozolomide capsules:
  - 1 time each day for 5 days in a row only, and then stop taking it for the next 23 days. This is 1 cycle of treatment (28 days).
  - Your healthcare provider will watch your progress on temozolomide and decide how long you should take it.
- If your healthcare provider prescribes a treatment regimen that is different from the information in this leaflet, make sure you follow the instructions given to you by your healthcare provider.
- Your healthcare provider may change your dose of temozolomide, or tell you to stop temozolomide capsules for a short period of time or permanently if you have certain side effects.

- Your healthcare provider will decide how many treatment cycles of temozolomide that you will receive, depending on how you respond to and tolerate treatment.

### Temozolomide capsules:

- Take temozolomide capsules exactly as your healthcare provider tells you to.
- Temozolomide capsules contain a white capsule body with a white cap and the imprinting ink colors vary based on the dosage strength. Your healthcare provider may prescribe more than 1 strength of temozolomide capsules for you, so it is important that you understand how to take your medicine the right way. Be sure that you understand exactly how many capsules you need to take on each day of your treatment, and what strengths to take. **This may be different whenever you start a new cycle.**
- **Do not take more temozolomide capsules than prescribed.**
- Talk to your healthcare provider or pharmacist before taking your dose if you are not sure how much temozolomide capsules to take. This will help to prevent taking too many temozolomide capsules and decrease your chances of getting serious side effects.
- Take each day's dose of temozolomide capsules at one time, with a full glass of water.
- Take temozolomide capsules at the same time each day.
- Take temozolomide capsules the same way each time, either with food or without food.
- **Swallow temozolomide capsules whole with water. Do not** open, chew, or dissolve the contents of the capsules.
- If temozolomide capsules are accidentally opened or damaged, be careful not to breathe in (inhale) the powder from the capsules or get the powder on your skin or mucous membranes (for example, in your nose or mouth). If contact with any of these

areas happens, wash the area with water right away.

- To help reduce nausea and vomiting, try to take temozolomide capsules on an empty stomach or at bedtime. Your healthcare provider may prescribe medicine to help prevent or treat nausea, or other medicines to reduce side effects with temozolomide capsules.
- See your healthcare provider regularly to check your progress. Your healthcare provider will check you for side effects.
- If you take more temozolomide capsules than prescribed, call your healthcare provider or get emergency medical help right away.

### What are the possible side effects of temozolomide capsules?

#### Temozolomide capsules can cause serious side effects, including:

- **Decreased blood cell counts.** Temozolomide capsules can affect your bone marrow and cause you to have decreased blood cell counts. Decreased white blood cell count, red blood cell count and platelet count are common with temozolomide capsules but it can also be severe and lead to death. Some people need to be hospitalized or need to receive transfusions to treat their decreased blood cell counts.
  - Your healthcare provider will do blood tests regularly to check your blood cell counts before you start and during treatment with temozolomide capsules.
  - Your healthcare provider may need to change the dose of temozolomide capsules or when you get it depending on your blood cell counts.
  - People who are age 70 or older and women have a higher risk for developing decreased blood cell counts during treatment with temozolomide capsules.

● **Liver problems. Liver problems can happen with temozolomide capsules and can sometimes be severe and lead to death.** Your healthcare provider will do blood tests to check your liver function before you start taking temozolomide capsules, during treatment, and about 2 to 4 weeks after your last dose of temozolomide capsules.

● ***Pneumocystis pneumonia (PCP)*.** PCP is an infection that people can get when their immune system is weak. Temozolomide capsules decreases white blood cells, which makes your immune system weaker and can increase your risk of getting PCP.

○ People who are taking steroid medicines or who stay on temozolomide capsules for a longer period of time may have an increased risk of getting PCP infection.

○ Anyone who takes temozolomide capsules will be watched carefully by their healthcare provider for low blood cell counts and this infection.

○ Tell your healthcare provider if you have any of the following signs and symptoms of PCP infection: shortness of breath, or fever, chills, dry cough.

● **Secondary Cancers.** Blood problems such as myelodysplastic syndrome (MDS) and new cancers (secondary cancers), including a certain kind of leukemia, can happen in people who take temozolomide capsules. Your healthcare provider will monitor you for this.

Common side effects of temozolomide capsules include:

- hair loss
- feeling tired
- nausea and vomiting
- headache
- constipation
- loss of appetite
- convulsions

Temozolomide capsules can affect fertility in males and may affect your ability to father a child. Talk with your healthcare provider if fertility is a concern for you.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of temozolomide capsules. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store temozolomide capsules?**

● Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).

● **Keep temozolomide capsules and all medicines out of the reach of children.**

#### **General information about the safe and effective use of temozolomide capsules.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use temozolomide capsules for a condition for which it was not prescribed. Do not give temozolomide capsules to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about temozolomide capsules that is written for health professionals.

#### **What are the ingredients in temozolomide capsules?**

**Active ingredient:** temozolomide.

**Inactive ingredients:** lactose anhydrous, sodium starch glycolate, tartaric acid, and stearic acid.

The capsule shell contains gelatin, titanium dioxide, and sodium lauryl sulfate.

The imprinting ink contains shellac, dehydrated alcohol, butyl alcohol, propylene glycol, strong ammonia solution, FD&C Blue # 1 Aluminum Lake (5 mg, 140 mg), yellow iron oxide (5 mg, 20 mg, 100 mg), red iron oxide (100 mg, 180 mg), titanium dioxide (100 mg, 140 mg), potassium hydroxide (100 mg, 250 mg) and black iron oxide (250 mg).

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This Patient Information has been approved by the U.S. Food and Drug Administration.