



Rx only

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 is the most important information I should know about temozolomide capsules? Temozolomide capsules may cause birth defects.

Females and female partners of male patients who take temozolomide capsules:

- Avoid becoming pregnant while taking temozolomide capsules.
- Females who can become pregnant should use an effective form of birth control (contraception) during treatment and for at least 6 months after your last dose of temozolomide capsules. Your doctor should do a pregnancy test to make sure that you are not pregnant before you start taking temozolomide capsules.
- Tell your doctor right away if you become pregnant or think you are pregnant during treatment with temozolomide capsules. Males taking temozolomide capsules and have a female partner who is pregnant or who can become pregnant:
- Use a condom for birth control (contraception) during treatment and for at least 3 months after taking your final dose of temozolomide capsules.
- Do not donate semen during treatment and for at least 3 months after your final dose of temozolomide capsules.

See the section "What are the possible side effects of temozolomide capsules?" for more information about side effects.

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.

Who should not take temozolomide capsules?

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 doctor.
- have had an allergic reaction to dacarbazine (DTIC), another cancer medicine.

What should I tell my doctor before taking temozolomide capsules?

Tell your doctor about all of your medical conditions, including if you:

- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. **See "What is the most important information I should know about temozolomide capsules?"**
- are breast-feeding or plan to breastfeed. It is not known if temozolomide passes into your breast milk. **Do not** breastfeed during treatment and for at least 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. Especially tell your doctor if you take a medicine that contains valproic acid.

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

How should I take temozolomide capsules?

Temozolomide capsules may be taken 2 different ways:

- you may take temozolomide by mouth as a capsule, **or**
- Your doctor will decide the best way for you to take temozolomide capsules. Take temozolomide capsules exactly as prescribed by your doctor.

There are 2 common dosing schedules for taking 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 days in a row (possibly 49 days depending on side effects) along with receiving radiation treatment. **This is 1 cycle of treatment.**
 - After this, your doctor 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 doctor will watch your progress on temozolomide and decide how long you should take it. You might take temozolomide capsules until your tumor gets worse or for possibly up to 2 years.

- If your doctor prescribes a treatment regimen that is different from the information in this leaflet, make sure you follow the instructions given to you by your doctor.
- Your doctor 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 doctor 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 doctor 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 doctor 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 doctor 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.

• Swallow temozolomide capsules whole. Do not chew, open, or split the capsules.

• Take temozolomide capsules at the same time each day.

• Take temozolomide capsules the same way each time, either with food or without food.

• 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, flush the area with water.

• To help reduce nausea and vomiting, try to take temozolomide capsules on an empty stomach or at bedtime. Your doctor may prescribe medicine to help prevent or treat nausea, or other medicines to reduce side effects with temozolomide capsules.

• See your doctor regularly to check your progress. Your doctor will check you for side effects. If you take more temozolomide capsules than prescribed, call your doctor or get emergency medical help right away.

What are the possible side effects of temozolomide capsules?

Temozolomide capsules can cause serious side effects, including:

- **See "What is the most important information I should know about temozolomide capsules?"**

- **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.
 - Your doctor will do blood tests regularly to check your blood cell counts before you start and during treatment with temozolomide capsules.
 - Your doctor 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.**
- **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 doctor will monitor you for this.
- ***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 doctor for low blood cell counts and this infection.

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

- **Liver problems. Liver problems can happen with temozolomide capsules and can sometimes be severe and lead to death.** Your doctor 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.

Common side effects of temozolomide capsules include:

- hair loss
- unable to move (paralysis) on one side of the body
- feeling tired
- weakness
- nausea and vomiting
- fever
- headache
- dizziness
- constipation
- coordination problems
- loss of appetite
- viral infection
- convulsions
- memory loss
- rash
- sleep problems
- diarrhea

Temozolomide capsules can affect fertility in males and may affect your ability to father a child. Talk with your doctor if fertility is a concern for you. Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects with temozolomide capsules. For more information, ask your doctor 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 the 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. This leaflet summarizes the most important information about temozolomide capsules. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about temozolomide capsules that is written for health professionals.

For more information, call 1-800-818-4555.

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).

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

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