

Patient Information

**TEMODAR® (tem-o-dar)
(temozolomide)
capsules**

**TEMODAR® (tem-o-dar)
(temozolomide)
for injection**

What is TEMODAR?

TEMODAR is a prescription medicine used to treat adults with certain brain cancer tumors. It is not known if TEMODAR is safe and effective in children.

Do not take TEMODAR if you:

- have had an allergic reaction to temozolomide or any of the other ingredients in TEMODAR. See the end of this leaflet for a list of ingredients in TEMODAR. Symptoms of an allergic reaction with TEMODAR 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 TEMODAR, 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. **TEMODAR can harm your unborn baby and cause birth defects.**

Females who can become pregnant:

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

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 TEMODAR.
- **Do not** donate semen during treatment and for 3 months after your last dose of TEMODAR.
- are breastfeeding or plan to breastfeed. It is not known if TEMODAR passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of TEMODAR.

Tell your doctor about all the medicines you take, including prescription and non-prescription 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 TEMODAR?

TEMODAR may be taken 2 different ways:

- you may take TEMODAR by mouth as a capsule, or
- you may receive TEMODAR as an intravenous (IV) injection into your vein.

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

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

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

- People with certain brain cancer tumors take or receive TEMODAR:
 - 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 TEMODAR as “maintenance” treatment. For each of these cycles, you take or receive TEMODAR 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 TEMODAR:
 - 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 TEMODAR 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 TEMODAR, or tell you to stop TEMODAR for a short period of time or permanently if you have certain side effects.
- Your healthcare provider will decide how many treatment cycles of TEMODAR that you will receive, depending on how you respond to and tolerate treatment.

TEMODAR capsules:

- Take TEMODAR capsules exactly as your healthcare provider tells you to.
- TEMODAR capsules contain a white capsule body with a color cap and the colors vary based on the dosage strength. Your healthcare provider may prescribe more than 1 strength of TEMODAR 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 TEMODAR than prescribed.**
- Talk to your healthcare provider or pharmacist before taking your dose if you are not sure how much TEMODAR to take. This will help to prevent taking too much TEMODAR and decrease your chances of getting serious side effects.
- Take each day’s dose of TEMODAR capsules at one time, with a full glass of water.
- Take TEMODAR capsules at the same time each day.
- Take TEMODAR the same way each time, either with food or without food.
- **Swallow TEMODAR capsules whole with water. Do not** open, chew, or dissolve the contents of the capsules.
- If TEMODAR 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 TEMODAR 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 TEMODAR.
- See your healthcare provider regularly to check your progress. Your healthcare provider will check you for side effects.
- If you take more TEMODAR than prescribed, call your healthcare provider or get emergency medical help right away.

TEMODAR for injection:

- You will receive TEMODAR as an infusion directly into your vein over about 90 minutes.
- Your healthcare provider may prescribe medicine to prevent or treat nausea, or other medicines to help relieve side effects with TEMODAR.
- For certain people taking or receiving TEMODAR, your healthcare provider may prescribe an antibiotic to prevent certain infections if you have certain white blood cell counts that are too low.

What are the possible side effects of TEMODAR?

TEMODAR can cause serious side effects, including:

- **Decreased blood cell counts.** TEMODAR 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 TEMODAR 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 TEMODAR.
 - Your healthcare provider may need to change the dose of TEMODAR 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 TEMODAR.
- **Liver problems. Liver problems can happen with TEMODAR 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 TEMODAR, during treatment, and about 2 to 4 weeks after your last dose of TEMODAR.
- ***Pneumocystis pneumonia (PCP).*** PCP is an infection that people can get when their immune system is weak. TEMODAR 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 TEMODAR for a longer period of time may have an increased risk of getting PCP infection.
 - Anyone who takes TEMODAR 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 TEMODAR. Your healthcare provider will monitor you for this.

Common side effects of TEMODAR include:

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

Additional side effects seen with TEMODAR for injection include:

- pain, irritation, itching, warmth, swelling, or redness at the site of infusion
- bruising or small red or purple spots under the skin

TEMODAR 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 TEMODAR. 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 TEMODAR capsules?

- Store TEMODAR capsules at room temperature between 68°F to 77°F (20°C to 25°C).

Keep TEMODAR and all medicines out of the reach of children.

General information about the safe and effective use of TEMODAR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

Do not use TEMODAR for a condition for which it was not prescribed. Do not give TEMODAR 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 TEMODAR that is written for health professionals.

What are the ingredients in TEMODAR?

TEMODAR capsules:

Active ingredient: temozolomide

Inactive ingredients: lactose anhydrous, colloidal silicon dioxide, sodium starch glycolate, tartaric acid, stearic acid.

The body of the capsules is made of gelatin and is opaque white. The cap is also made of gelatin, and the colors vary based on the dosage strength. The capsule body and cap are imprinted with pharmaceutical branding ink, which contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, purified water, strong ammonia, potassium hydroxide, and ferric oxide.

TEMODAR 5 mg: The green cap contains gelatin, titanium dioxide, iron oxide yellow, sodium lauryl sulfate, and FD&C Blue #2.

TEMODAR 20 mg: The yellow cap contains gelatin, sodium lauryl sulfate, and iron oxide yellow.

TEMODAR 100 mg: The pink cap contains gelatin, titanium dioxide, sodium lauryl sulfate, and iron oxide red.

TEMODAR 140 mg: The blue cap contains gelatin, sodium lauryl sulfate, and FD&C Blue #2.

TEMODAR 180 mg: The orange cap contains gelatin, iron oxide red, iron oxide yellow, titanium dioxide, and sodium lauryl sulfate.

TEMODAR 250 mg: The white cap contains gelatin, titanium dioxide, and sodium lauryl sulfate.

TEMODAR for injection:

Active ingredient: temozolomide.

Inactive ingredients: mannitol, L-threonine, polysorbate 80, sodium citrate dihydrate, and hydrochloric acid.

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For more information, go to www.TEMODAR.com or call 1-877-888-4231.

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

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