

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TEMODAL®

temozolomide capsules

Read this carefully before you start taking **TEMODAL®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TEMODAL®**.

Serious Warnings and Precautions

- **TEMODAL®** should be prescribed by doctor experienced with the use of cancer drugs.
- **TEMODAL®** may cause serious side effects including:
 - **Myelosuppression:** This is a severe decrease in the production of blood cells including white blood cells (**neutropenia**), red blood cells (**anemia**) and platelets (**thrombocytopenia**). **Aplastic anemia** is also possible. This is when the body stops making enough new blood cells. It may be life threatening.
 - **Liver problems** which may be life threatening.

What is TEMODAL® used for?

- **TEMODAL®** is used to treat adults with:
 - Glioblastoma multiforme that:
 - was recently diagnosed. These patients will also be treated with radiation.
 - that has come back or gotten worse after other treatment.
 - Anaplastic astrocytoma that has come back or gotten worse after other treatment.

How does TEMODAL® work?

TEMODAL® is an antitumor agent. It acts on cancer cells. Normal cells may also be affected which may lead to side effects.

What are the ingredients in TEMODAL®?

Medicinal ingredient: temozolomide

Non-medicinal ingredients: ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD & C blue no. 2 (5 mg and 140 mg), gelatin, lactose anhydrous, propylene glycol, potassium hydroxide, red iron oxide (100 mg), sodium lauryl sulphate, shellac, sodium starch glycolate, stearic acid, tartaric acid, titanium dioxide and yellow iron oxide (5 mg and 20 mg).

TEMODAL® comes in the following dosage forms:

Capsules: 5 mg (white and green), 20 mg (white and yellow), 100 mg (white and pink), 140 mg (white and blue) or 250 mg (white).

Do not use TEMODAL® if:

- you are allergic to temozolomide or to any other ingredients in this medicine.
- you have had an allergic reaction to dacarbazine (DTIC), another drug used to treat cancer.

- you have low blood cell counts (severe myelosuppression).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TEMODAL®. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- have kidney problems.
- have or have had hepatitis B infection. This is because patients who have had hepatitis B in the past, might have a repeat attack after treatment with TEMODAL®.
- have other diseases or conditions.
- have an infection including herpes simplex encephalitis (inflammation of the brain).
- are over 70 years of age.
- are also taking steroid medicines.

Other warnings you should know about:

Nausea and vomiting are very common with the use of TEMODAL®. For this reason, your healthcare professional may recommend that you also take medicines to treat and prevent these side effects. Your healthcare professional will tell you the best time to take TEMODAL® until the vomiting is under control.

Female patients – pregnancy and breastfeeding:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not use TEMODAL® if you are pregnant. It may harm your unborn baby.
- Avoid becoming pregnant while you are taking TEMODAL® and for 6 months after your last dose.
- Use effective birth control during your treatment for 6 months after your last dose.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with TEMODAL®.
- Do not breastfeed while you are taking TEMODAL®. It is not known if it passes into breastmilk.

Male patients – pregnancy and fertility:

- Avoid fathering a child while you are taking TEMODAL® and for at least 6 months after your last dose. Use effective birth control during your treatment.
- Taking TEMODAL® may affect your ability to father a child (your fertility). This may be permanent. If you want to have a child in the future, you may want to preserve some semen. Talk to your healthcare professional if you have questions about this.

Driving and using machines: Do not drive or use machines until you know how you react to TEMODAL®.

***Pneumocystis carinii*:** This type of severe pneumonia has been seen when TEMODAL® is used with radiation. If you will receive TEMODAL® for the 42 day treatment regimen, your healthcare professional will also give you medicines to prevent *Pneumocystis carinii*.

Blood tests: Your healthcare professional will do blood tests before and during your treatment. The results of these tests will tell them how TEMODAL® is affecting your blood and liver.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TEMODAL®:

- A medicine used to treat seizures called valproic acid.
- Other chemotherapy drugs used to treat cancer such as bendamustine, carboplatin and cisplatin.

How to take TEMODAL®:

- Take TEMODAL®:
 - exactly as your healthcare professional has told you. If you are not sure, ask your doctor, nurse or pharmacist.
 - on an empty stomach, at least one hour before a meal.
 - Swallow the capsule (s) whole with a glass of water. Do not open or chew the capsule.
 - Avoid contact with your skin, eyes, and nose.
 - You may also be given other medicines to prevent nausea and vomiting.

Usual dose: The dose of TEMODAL® will be different for each adult. Your doctor will determine the dose of TEMODAL® that is right for you. It will be based on your height and weight (m²), your disease and whether you have had previous treatment.

Your doctor will tell you how much TEMODAL® to take. They will also tell you when to take it and for how long.

Overdose:

If you think you, or a person you are caring for, have taken too much TEMODAL®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, or vomit after taking a dose, contact your doctor for instructions.

What are possible side effects from using TEMODAL®?

These are not all the possible side effects you may have when taking TEMODAL®. If you experience any side effects not listed here, tell your healthcare professional.

- Hair loss
- Fatigue
- Shortness of breath
- Chills
- Nausea (feeling sick)
- Inflamed and sore mouth
- Constipation
- Change in taste
- Headache

- Fever
- Cough
- Muscle weakness
- Sleepiness
- Trouble sleeping
- Trouble hearing
- Dizziness
- Tremor
- Tingling sensation
- Anxiety
- Depression
- Changes in emotions
- Pain, pain in the joints, abdominal pain
- Itching
- Dry skin
- Skin redness
- Difficulty speaking
- Damage to the skin or tissue under the skin from radiation

TEMODAL® can cause abnormal blood test results. Your healthcare professional will monitor your blood regularly for any changes. They will decide if any specific treatment is needed. In some cases, your TEMODAL® dose will be reduced or discontinued.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Blurred vision		√	
Loss of appetite		√	
Myelosuppression (low blood cell counts): Anemia (low red blood cells): shortness of breath, feeling very tired, loss of energy, weakness, irregular heartbeat, pale complexion. Neutropenia (low white blood cells): fever, fatigue, aches, pains, flu-like symptoms Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
Rash		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Vomiting		√	
COMMON			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat		√	
Bleeding: seizures, loss of consciousness, severe headache, tingling, weakness, numbness or paralysis of face, arm or leg, vomiting up blood, black and tarry stool, bleeding from the rectum, abdominal pain, blood in urine		√	
Confusion		√	
Convulsion		√	
Diarrhea		√	
Hyperglycemia: (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		√	
Infection: fever, chills, cough		√	
Loss of weight		√	
Memory problems		√	
<i>Pneumocystis carinii</i> pneumonia (severe infection of the lungs caused by fungus): cough that does not go away, trouble breathing, and fever		√	
UNCOMMON			
Severe allergic reactions: hives, itching, flushed or pale skin, low blood pressure, swollen tongue or throat, wheezing, difficulty breathing, weak and rapid heartbeat, nausea, vomiting, diarrhea, dizziness, fainting			√
UNKNOWN FREQUENCY			
Aplastic anemia (body stops producing enough new blood cells): fatigue, pale skin, shortness of breath, rapid heart beat, fever, bleeding		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Cytomegalovirus infection (viral infection that is new or becomes active again): fatigue, fever, sore throat, muscle aches, swollen glands		√	
Drug reaction with eosinophilia and systemic symptoms (DRESS; serious skin reaction that may affect one or more organs): fever, severe rash, peeling skin, swelling of the face and lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine		√	
Erythema multiforme (serious skin reaction): rash with skin swelling, including on the palms of the hands and soles of the feet		√	
Herpes simplex encephalitis (inflammation of the brain): fever, headache, personality change, seizures, and/or vomiting, which may be life threatening.			√
Interstitial pneumonitis (scarring of the lung): shortness of breath, cough		√	
Liver problems including jaundice, hepatitis and liver failure: loss of appetite, abdominal pain, yellowing of the whites of they eyes, skin and tongue (jaundice), may be life threatening		√	
Myelodysplastic syndrome or other cancers including myeloid leukemia: fatigue, pale skin, easy or unusual bruising, bleeding, shortness of breath, weight loss, fever, loss of appetite, tiny red spots on your skin		√	
Serious skin reactions including Toxic epidermal necrolysis and			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Stevens-Johnson syndrome: painful reddening of the skin and/or blister on the body or the mouth			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C. Protect from moisture.
Do not use this product after the expiration date on the package.

Keep out of reach and sight of children.

Tell your pharmacist if you notice any change in the appearance of the capsules.

If you want more information about TEMODAL®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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