

# TEMODAL®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using TEMODAL?

TEMODAL contains the active ingredient temozolomide. TEMODAL belongs to a group of medicines called cytotoxic or chemotherapy medicines. TEMODAL works by killing cancer cells and stopping cancer cells from growing and multiplying.

For more information, see Section [1. Why am I using TEMODAL?](#) in the full CMI.

### 2. What should I know before I use TEMODAL?

Do not use if you have ever had an allergic reaction to TEMODAL or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use TEMODAL?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with TEMODAL and affect how it works. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use TEMODAL?**

- Your doctor has worked out the exact dose of TEMODAL for you according to your individual needs.
- Each time you start a new treatment cycle, be sure you understand exactly how many capsules of each strength you need to take on each day of dosing.

More instructions can be found in Section [4. How do I use TEMODAL?](#) in the full CMI.

## 5. What should I know while using TEMODAL?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using TEMODAL.</li><li>• Tell your doctor if you feel sick or vomit while being treated with TEMODAL</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not open the capsules. If a capsule is damaged, avoid contact with your skin, eyes and nose. Avoid inhaling the powder. If you touch the powder or get some in your eyes or nose, wash the area with water.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how TEMODAL affects you.</li><li>• As with other medicines, TEMODAL may make some people feel tired. If this occurs do not drive.</li></ul>

### Looking after your medicine

- Keep your TEMODAL capsules in the sachet pack until it is time to use them.
- Keep TEMODAL in a cool dry place where the temperature stays below 25°C.
- Follow the instructions in the carton on how to take care of your medicine properly.

For more information, see Section [5. What should I know while using TEMODAL?](#) in the full CMI.

## 6. Are there any side effects?

Like all medicines, TEMODAL can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using TEMODAL. When you get TEMODAL, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TEMODAL

**Active ingredient:** *temozolomide*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using TEMODAL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TEMODAL.**

**Where to find information in this leaflet:**

- [1. Why am I using TEMODAL?](#)
- [2. What should I know before I use TEMODAL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TEMODAL?](#)
- [5. What should I know while using TEMODAL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using TEMODAL?

**TEMODAL contains the active ingredient temozolomide.** TEMODAL is belongs to a group of medicines called cytotoxic or chemotherapy medicines.

TEMODAL works by killing cancer cells and stopping cancer cells from growing and multiplying.

**TEMODAL is used to treat patients with brain tumours. TEMODAL is also used to treat adult patients with advanced metastatic malignant melanoma.**

Your doctor, however, may prescribe TEMODAL for another purpose.

### **Use in children**

TEMODAL capsules are used to treat children 3 years and older, with specific forms of brain tumour (glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy).

Ask your doctor if you have any questions about why TEMODAL has been prescribed for you.

## **2. What should I know before I use TEMODAL?**

### **Warnings**

#### **Do not use TEMODAL if:**

**You are allergic to TEMODAL (temozolomide), dacarbazine (DTIC) or any of the ingredients listed at the end of this leaflet.**

**You are pregnant or intend to become pregnant (see Pregnancy).**

**You are breastfeeding (see Breastfeeding).**

**You have a very low level of white blood cells, red blood cells or platelets (myelosuppression).**

Symptoms of an allergic reaction may include:

- hives, itching or skin rash
- swelling of the face, lips or tongue. This may lead to difficulty swallowing.
- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest.

Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

**Vomit frequently.**

Your doctor may give you medicine to control the vomiting.

**Are anaemic or have blood clotting problems.**

**Intend to have children.**

TEMODAL may cause infertility in men.

**Have liver or kidney problems.**

TEMODAL could cause hepatitis B to become active again, which can be fatal in some cases.

**Have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

**Have any other medical conditions.**

**Take any medicines for any other condition.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy**

Check with your doctor if you are pregnant or intend to become pregnant.

TEMODAL may cause birth defects if either the male or female is using TEMODAL at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before starting TEMODAL.

Both male and female patients and their partners should each use some kind of birth control while taking TEMODAL and also after the last dose. Female patients should continue to use an effective form of birth control for at least 6 months and male patients to continue for at least 3 months after the final dose. Male patients whose partners are already pregnant should use a condom to minimise exposure of the unborn baby to TEMODAL in the sperm. Also, do not donate sperm during and for at least 3 months after the final dose due to the potential effects on sperm.

## **Breastfeeding**

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by TEMODAL or may affect how well TEMODAL works. These include other medicines used to treat cancer or any other treatment that may lower your immune system. You may need different amounts of your medicine or you may need to use different medicines. Your doctor will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TEMODAL.**

### **4. How do I use TEMODAL?**

#### **How much to take**

Your doctor has worked out the exact dose of TEMODAL for you according to your individual needs.

You may be given other medication to take before or after TEMODAL to help stop nausea.

**If you are taking TEMODAL in combination treatment with radiation (newly diagnosed patients):**

If you are a patient with a newly diagnosed brain tumour, your doctor will start you on a dose of TEMODAL every day for 42 days (up to 49 days) in combination with radiation therapy. This is the first part of the treatment ("concomitant phase") in which you complete the radiation therapy. Your treatment will be interrupted for 4 weeks to give your body a chance to recover.

Then, you will start the next phase of treatment ("adjuvant phase") and your TEMODAL dose will change. In this phase, there are up to 6 treatment cycles. Each treatment cycle lasts 28 days. You will take your new dose of TEMODAL capsules once daily for the first five days ("dosing days") of each cycle, followed by 23 days without TEMODAL; this adds up to a 28 day treatment cycle. After day 28, the next cycle will begin, in which you will again take this medicine once daily for five days followed by 23 days without TEMODAL. Before each new treatment cycle begins, your blood will be tested to determine if the TEMODAL dose needs to be adjusted.

**If you are taking only TEMODAL (patients treated for recurrent brain tumour):**

Take the dose the doctor has prescribed once a day for five days. Depending on your response to TEMODAL, a new treatment cycle will begin each 28 days. You will then take this medicine again once daily for five days.

Before each new treatment cycle, your blood will be tested to see if the dose needs to be changed

## How to take TEMODAL

Each time you start a new treatment cycle, be sure you understand exactly how many capsules of each strength you need to take on each day of dosing.

### All patients

TEMODAL comes in different strength capsules (shown on the outer label in mg). Each strength is a different colour. Depending on the dose of TEMODAL that your doctor prescribes, you may have to take several capsules on each dosing day of the treatment cycle

Be sure you understand exactly how many capsules you need to take of each strength. Ask your doctor or pharmacist to write down the number and strength (including colour) that you need to take on each dosing day.

Be sure you know exactly which days are your dosing days.

Be sure you review the dose with your health care provider each time you start a new cycle. Sometimes the dose or the mix of capsules you need to take will be different from the last cycle.

**Once you take the medicine home, if you are confused or unsure about how to take your dose, call for re-instruction before beginning the treatment cycle. Errors in how you take this medicine may have serious health consequences**

## **When to take TEMODAL**

Take TEMODAL without food at least one hour before a meal. Swallow the capsules whole with a glass of water. Do not open or chew the capsules

It is good practice to take TEMODAL at about the same time each day.

If vomiting occurs after you take your capsules, do not take another dose that day.

## **How long to take TEMODAL**

Your doctor will tell you when your treatment should be stopped.

## **If you forget to use TEMODAL**

TEMODAL should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as possible during the same day. If a full day has gone by, check with your doctor.

Do not double the next dose unless your doctor tells you to do so.

## **If you use too much TEMODAL**

If you think that you have used too much TEMODAL, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using TEMODAL?**

### **Things you should do**

**Tell all doctors, dentists and pharmacists who are treating you that you are being treated with TEMODAL.**

**Tell your doctor if you feel sick or vomit while being treated with TEMODAL.**

Your doctor may give you another medicine to help stop this.

**Tell your doctor if you become unusually pale or tired, get blood clotting problems or frequent infections while being treated with TEMODAL.**

These could be caused by a low level of red blood cells, platelets or white blood cells in the blood. This is more common in patients over 70 years of age. Your doctor may need to change your dose of TEMODAL.

**If you or your partner becomes pregnant while you are being treated with TEMODAL, tell your doctor.**

**Be sure to keep all your doctor's appointments so your progress can be checked.**

Your doctor may need to do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of TEMODAL at the appropriate times to get the best effects from your treatment.

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with TEMODAL.**

## **Things you should not do**

- Do not open the capsules. If a capsule is damaged, avoid contact with your skin, eyes and nose. Avoid inhaling the powder. If you touch the powder or get some in your eyes or nose, wash the area with water.
- Do not give TEMODAL to anyone else, even if they have the same condition as you.
- Do not use TEMODAL to treat any other complaints unless your doctor tells you to.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TEMODAL affects you.**

As with other medicines, TEMODAL may make some people feel tired. If this occurs do not drive.

## **Looking after your medicine**

- Keep your TEMODAL capsules in the sachet pack until it is time to use them.
- Keep TEMODAL in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

- Do not use TEMODAL after the expiry date printed on the pack.
- Do not use TEMODAL if the packaging shows signs of tampering.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Like other medicines, TEMODAL may have unwanted side effects. Sometimes they may be serious, most of the time they are not. You may need medical attention if you get some of these side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• nausea, vomiting, feeling unwell</li><li>• tiredness, sleepiness</li><li>• constipation</li><li>• headache</li><li>• loss of appetite or weight</li><li>• diarrhoea</li><li>• fever or high temperature</li><li>• rash, hair loss, itching</li><li>• dizziness, weakness</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● general body pain</li> <li>● stomach pain, indigestion</li> <li>● different taste sensation</li> <li>● mouth ulcers</li> <li>● coughing</li> <li>● sleeplessness</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● shortness of breath</li> <li>● tingling or numbness in hands or feet</li> <li>● bruising, bleeding or being unusually pale or tired</li> </ul> <p>This could be caused by a low level of platelets or red blood cells in the blood.</p> <ul style="list-style-type: none"> <li>● new or recurring cytomegalovirus infection and return of hepatitis B</li> <li>● symptoms of diabetes include passing large</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>amount of urine and constant thirst</p> <ul style="list-style-type: none"> <li>● symptoms such as fever, headache, personality change, seizures, and/or vomiting which could be associated with a brain infection caused by herpes virus.</li> <li>● shivering that is associated with chills and fever. This could be sign of an infection caused by a low level of white blood cells in the blood.</li> <li>● development of red or purple spots under the skin</li> </ul> <p>These last two side effects of TEMODAL may take some time to occur. Therefore, even after you have finished your treatment with TEMODAL, you should tell your doctor immediately if you notice these side effects.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What TEMODAL contains**

<b>Active ingredient (main ingredient)</b>	Temozolomide
<b>Other ingredients (inactive ingredients)</b>	lactose sodium starch glycollate

stearic acid

tartaric acid

colloidal anhydrous silica

**The capsule shells also contain the following ingredients:**

gelatin

titanium dioxide

sodium lauryl sulfate

Indigo Carmine

(TEMODAL 5 mg and 140 mg)

Iron Oxide Yellow

(TEMODAL 5 mg, 20 mg and 180 mg)

Iron Oxide Red

(TEMODAL 100 mg and 180 mg)

TEMODAL does not contain sucrose, gluten, tartrazine or other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What TEMODAL looks like**

TEMODAL capsules have the word "TEMODAL" printed on one part of the capsule and "the strength", two stripes and the Schering-Plough logo printed on the other part. The colour of the printing is black

TEMODAL 5 mg capsules are white and green (AUST R 164210).

TEMODAL 20 mg capsules are white and yellow (AUST R 164211).

TEMODAL 100 mg capsules are white and pink (AUST R 164212).

TEMODAL 140 mg capsules are white and blue (AUST R 164213).

TEMODAL 180 mg capsules are white and orange (AUST R 164215).

TEMODAL 250 mg capsules are white (AUST R 164216).

## **Who distributes TEMODAL**

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

Australia

This leaflet was prepared in January 2024

RCN: 000024797-AU

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