

TEMODAL[®] CAPSULE

Temozolomide (20 mg, 100 mg)

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What TEMODAL is used for

TEMODAL is used for the treatment of specific forms of brain tumours:

- in people with newly-diagnosed brain tumour concomitantly with radiotherapy and then as adjuvant treatment.
- in people with malignant brain tumour, showing recurrence or progression after standard therapy.

How TEMODAL works

TEMODAL contains a medicine called temozolomide. This medicine is an antitumour agent. It works by killing cancer cells and stopping cancer cells from growing and multiplying.

Before you take TEMODAL

- When you must not take it

Do not take TEMODAL

- if you are allergic to ‘temozolomide dacarbazine’ (DTIC) or any of the other ingredients of this medicine (listed in “**Product Description**”). Signs of allergic reaction include hives, itchy or skin rash, swelling of the face, lips, tongue or throat, breathlessness, wheezing, or a tight feeling in your chest.
- if you or your partner are pregnant or intend to become pregnant.
- if you are breastfeeding.
- if you have a very low level of white blood cells, red blood cells or platelets.

- Before you start to take it

Talk to your doctor, pharmacist or nurse before taking TEMODAL,

- if you vomit frequently. Your doctor may give you medicine to control the vomiting.
- if you are anaemic or have blood clotting problems.
- if you intend to have children. TEMODAL may cause infertility in men.
- if you have liver or kidney problems. TEMODAL could cause hepatitis B to become active again, which can be fatal in some cases.
- if you have allergies to any other medicines, any other substances such as food, preservatives or dyes.

Children and adolescents

Do not give this medicine to children under the age of 3 years because it has not been studied. There is limited information in children over 3 years of age who have taken TEMODAL.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. This is because you must not be treated with TEMODAL during pregnancy unless clearly indicated by your doctor. TEMODAL may cause potential hazard to the fetus if either the male or female is using TEMODAL at the time of conception or during pregnancy. Therefore, females must have a negative pregnancy test before starting TEMODAL. Effective contraceptive precautions must be taken by **female patients** who are able to become pregnant during treatment with TEMODAL and for at least 6 months after the final dose. Males whose partners are already pregnant should use a condom to minimise exposure of the unborn baby to TEMODAL in the sperm (see also “Male fertility” below).

You should stop breast-feeding while receiving treatment with TEMODAL.

Male fertility

TEMODAL may cause permanent infertility. Male patients should use effective contraception and not father a child for at least 3 months after the final dose. Advise male patients not to donate semen during treatment with TEMODAL and for at least 3 months after the final dose. It is recommended to seek advice on conservation of sperm prior to treatment.

TEMODAL contains lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially valproic acid (used to treat and prevent seizure).

How to take TEMODAL

- How much to take

Your doctor will work out your dose of TEMODAL. This is based on your size (height and weight) and if you have a recurrent tumour and have had chemotherapy treatment in the past. You may be given other medicines (anti-emetics) to take before and/or after taking TEMODAL to prevent or control nausea and vomiting.

People with newly-diagnosed brain tumour:

If you are newly-diagnosed, treatment will occur in two phases:

- treatment together with radiotherapy (concomitant phase) first
- followed by treatment with only TEMODAL (monotherapy phase).

During the concomitant phase, your doctor will start TEMODAL at a dose of 75 mg/m² (usual dose). You will take this dose every day for 42 days (up to 49 days) in combination with radiotherapy. The TEMODAL dose may be delayed or stopped, depending on your blood counts and how you

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tolerate your medicine during the concomitant phase.
Once the radiotherapy is completed, you will interrupt treatment for 4 weeks. This will give your body a chance to recover.
Then, you will start the adjuvant phase.

During the adjuvant phase, the dose and way you take TEMODAL will be different. Your doctor will work out your exact dose. There may be up to 6 treatment periods (cycles). Each one lasts 28 days. You will take your new dose of TEMODAL alone once daily for the first 5 days ("dosing days") of each cycle. The first dose will be 150 mg/m². Then you will have 23 days without TEMODAL. This adds up to a 28-day treatment cycle.

After Day 28, the next cycle will begin. You will again take TEMODAL once daily for 5 days followed by 23 days without TEMODAL. The TEMODAL dose may be adjusted, delayed or stopped depending on your blood counts and how you tolerate your medicine during each treatment cycle.

People with tumours that have returned or worsened taking TEMODAL only:

A treatment cycle with TEMODAL lasts 28 days.
You will take TEMODAL alone once daily for the first 5 days. This daily dose depends on whether or not you have received chemotherapy before.

If you have not been previously treated with chemotherapy, your first dose of TEMODAL will be 200 mg/m² once daily for the first 5 days. If you have been previously treated with chemotherapy, your first dose of TEMODAL will be 150 mg/m² once daily for the first 5 days.
Then, you will have 23 days without TEMODAL. This adds up to a 28-day treatment cycle.

After Day 28, the next cycle will begin. You will again receive TEMODAL once daily for 5 days, followed by 23 days without TEMODAL.

Before each new treatment cycle, your blood will be tested to see if the TEMODAL dose needs to be adjusted. Depending on your blood test results, your doctor may adjust your dose for the next cycle.

- When to take it

Take your prescribed dose of TEMODAL once a day, preferably at the same time each day.

Take the capsules on an empty stomach; for example, at least one hour before you plan to have a meal. Swallow the capsule(s) whole with a glass of water. Do not open, crush or chew the capsules.

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

If a capsule is damaged, avoid contact of the powder with your skin, eyes or nose. If you accidentally get some in your eyes or nose, flush the area with water.

Depending on the prescribed dose, you may have to take more than one capsule together, eventually with different strengths (content of active substance, in mg). The colour of the capsule cap is different for each strength (see in the table below).

Strength	Colour of the cap
TEMODAL Capsule 20 mg	yellow
TEMODAL Capsule 100 mg	pink

You should make sure you fully understand and remember the following:

- how many capsules you need to take every dosing day. Ask your doctor or pharmacist to write it down (including the colour).
- which days are your dosing days.

Review the dose with your doctor each time you start a new cycle, since it may be different from the last cycle.

Always take TEMODAL exactly as your doctor has told you. It is very important to check with your doctor or pharmacist if you are not sure. Errors in how you take this medicine may have serious health consequences.

- How long to take it

Continue taking TEMODAL for as long as your doctor recommends.

- If you forget to take it

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 take a double dose to make up for a forgotten dose, unless your doctor tells you to do so.

- If you take too much (overdose)

If you accidentally take more TEMODAL capsules than you were told to, you could develop low blood cell count, fever, organ failure, and possibly death. Therefore, contact your doctor, pharmacist or nurse immediately.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

While you are taking TEMODAL

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking TEMODAL capsule.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give TEMODAL to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

TEMODAL may make you feel tired or sleepy. In this case, do not drive or use any tools or machines or cycle until you

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see how this medicine affects you (see “Side effects”).

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following:

Infections:

- Fever, shivering, feeling unwell, sore throat, infections including oral and wound infections

Blood:

- Bruising, bleeding, being unusually pale or tired due to reduced number of blood cells

Metabolism:

- Loss of appetite, loss of weight; symptoms of increased sugar in the blood including constant thirst or passing a large amount of urine

Psychiatric:

- Changes in emotions, feeling anxious or depressed, inability to fall or stay asleep

Nerve:

- Seizure, headache, dizziness, sleepiness, shaking, forgetfulness, confusion, difficulty concentrating, difficulty speaking, impaired or tingling sensation, impaired balance

Eye:

- Double vision, abnormal or blurry vision

Ear:

- Hearing impairment, ringing in the ears

Vascular:

- Blood clot in the legs, fluid retention, swollen legs

Respiratory:

- Cough, shortness of breath

Gastrointestinal:

- Indigestion, difficulty swallowing, inflamed or sore mouth, abdominal pain, nausea, vomiting, constipation, diarrhea

Liver:

- Liver enzyme elevation

Skin:

- Rash, hair loss, itching, dry skin, redness, inflammation

Musculoskeletal:

- Weakness, muscle aches and pains, painful joint

Kidney:

- Difficulty holding your urine, frequent urination

General:

Allergic reaction, face swelling, general body pain, radiation injury, different taste sensation

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effect to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TEMODAL

- Storage

Keep this medicine out of the sight and reach of children, preferably in a locked cupboard. Accidental ingestion can be lethal for children.

Store below 30 °C.

Bottle presentation

- 1) Store in the original bottle in order to protect from moisture.
- 2) Keep the bottle tightly closed.

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

- Disposal

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

TEMODAL Capsule 20 mg is a yellow cap with white opaque body; its cap is imprinted in black ink with “TEMODAL”, while the body is imprinted in black ink with SP logo, “20 mg” and two stripes.

TEMODAL Capsule 100 mg is a pink, opaque cap and white, opaque body; its cap is imprinted in black ink with “TEMODAL”, while the body is imprinted in black ink with SP logo, “100 mg” and two stripes.

Bottle presentation

The capsules are dispensed in amber glass bottles with child-resistant closure. Each bottle contains 5 capsules of TEMODAL Capsules 20 mg or 100 mg.

The carton contains 1 bottle.

Sachet presentation

Each sachet contains 1 capsule. Each carton contains 5 capsules, individually sealed in sachets.

Not all pack sizes may be marketed.

- Ingredients

Active ingredient:

TEMODAL Capsule 20mg: Each capsule contains 20 mg *temozolomide*.
TEMODAL Capsule 100mg: Each capsule contains 100 mg *temozolomide*.

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Inactive ingredient:

The inactive ingredients are:

lactose anhydrous, colloidal silicon dioxide, sodium starch glycolate, tartaric acid, and stearic acid. Gelatin capsule shells contain titanium dioxide, iron oxide red and sodium lauryl sulphate. The capsules are imprinted with pharmaceutical ink.

- *MAL number*

TEMODAL Capsule 20mg:

MAL07082880ACRZ

TEMODAL Capsule 100mg:

MAL07082881ACRZ

Manufacturer

Orion Pharma, Turku, Finland.

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn.
Bhd.

Lot No. B-22-1 & B-22-2, Level 22

The Ascent, Paradigm No. 1

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