



Patient information leaflet
(For All Products not subject to Medical Prescription)

TEMOTERO 20 (Temozolomide Capsules 20 mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Temozolomide capsule is and what it is used for
2. What you need to know before you take Temozolomide capsule
3. How to take Temozolomide capsule
4. Possible side effects
5. How to store Temozolomide capsule
6. Contents of the pack and other information

1. WHAT TEMOZOLOMIDE CAPSULE IS AND WHAT IT IS USED FOR

Temozolomide Capsule contains a medicine called temozolomide. This medicine is an antitumour agent.

Temozolomide Capsule is used for the treatment of specific forms of brain tumours:

- in adults with newly-diagnosed glioblastoma multiforme. Temozolomide Capsule is first used together with radiotherapy (concomitant phase of treatment) and after that alone (monotherapy phase of treatment).

- in children 3 years and older and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma. Temozolomide Capsule is used in these tumours if they return or get worse after standard treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEMOZOLOMIDE CAPSULE

Do not take Temozolomide Capsule

- if you are allergic to temozolomide or any of the other ingredients of this medicine.
- if you have had an allergic reaction to dacarbazine (an anticancer medicine sometimes called DTIC). Signs of allergic reaction include feeling itchy, breathlessness or wheezing, swelling of the face, lips, tongue or throat.
- if certain kinds of blood cells are severely reduced (myelosuppression), such as your white blood cell count and platelet count. These blood cells are important for fighting infection and for proper blood clotting. Your doctor will check your blood to make sure you have enough of these cells before you begin treatment.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Temozolomide Capsule,

- as you should be observed closely for the development of a serious form of chest infection called *Pneumocystis jirovecii* pneumonia (PCP). If you are a newly-diagnosed patient (glioblastoma multiforme) you may be receiving Temozolomide Capsule for 42 days in combination with radiotherapy. In this case, your doctor will also prescribe medicine to help you prevent this type of pneumonia (PCP).
- if you have low counts of red blood cells (anaemia), white blood cells and platelets, or blood clotting problems before starting the treatment, or if you develop them during treatment. Your doctor may decide to reduce the dose, interrupt, stop or change your treatment. You may also need other treatments. In some cases, it may be necessary to stop treatment with Temozolomide Capsule. Your blood will be tested frequently during treatment to monitor the side effects of Temozolomide Capsule on your blood cells.
- as you may have a small risk of other changes in blood cells, including leukaemia.
- if you have nausea (feeling sick in your stomach) and/or vomiting which are very common side effects of Temozolomide Capsule, your doctor may prescribe you a medicine (an anti-emetic) to help prevent vomiting. If you vomit frequently before or during treatment, ask your doctor about

TEMOTERO 20
(Temozolomide Capsules 20 mg)



the best time to take Temozolomide Capsule until the vomiting is under control. If you vomit after taking your dose, do not take a second dose on the same day.

- if you develop fever or symptoms of an infection, contact your doctor immediately.
- if you are older than 70 years of age, you might be more prone to infections, bruising or bleeding.
- if you have liver or kidney problems, your dose of Temozolomide Capsule may need to be adjusted.

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 patients over 3 years of age who have taken Temozolomide Capsule.

Other medicines and Temozolomide Capsule

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Temozolomide Capsule during pregnancy unless clearly indicated by your doctor.

Effective contraceptive precautions must be taken by **both male and female patients** who are taking Temozolomide Capsule (see also “Male fertility” below).

You should stop breast-feeding while receiving treatment with Temozolomide Capsule.

Male fertility

Temozolomide Capsule may cause permanent infertility. Male patients should use effective contraceptions and not father a child for up to 6 months after stopping treatment. It is recommended to seek advice on conservation of sperm prior to treatment.

Driving and using machines

Temozolomide Capsule may make you feel tired or sleepy. In this case, do not drive or use any tools or machines or cycle until you see how this medicine affects you.

Temozolomide Capsule contains lactose

Temozolomide Capsule 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.

3. HOW TO TAKE TEMOZOLOMIDE CAPSULE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage and duration of treatment

Your doctor will work out your dose of Temozolomide Capsule. 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 Temozolomide Capsule to prevent or control nausea and vomiting.

Patients with newly-diagnosed glioblastoma multiforme:

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

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

During the concomitant phase, your doctor will start Temozolomide Capsule 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 Temozolomide Capsule dose may be delayed or stopped, depending on your blood counts and how you 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 monotherapy phase.

During the monotherapy phase, the dose and way you take Temozolomide Capsule 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 Temozolomide Capsule 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 Temozolomide Capsule. This adds up to a 28-day treatment cycle.

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

TEMOTERO 20
(Temozolomide Capsules 20 mg)

Patients with tumours that have returned or worsened (malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma) taking Temozolomide Capsule only:

A treatment cycle with Temozolomide Capsule lasts 28 days.

You will take Temozolomide Capsule 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 Temozolomide Capsule will be 200 mg/m² once daily for the first 5 days. If you have been previously treated with chemotherapy, your first dose of Temozolomide Capsule will be 150 mg/m² once daily for the first 5 days.

Then, you will have 23 days without Temozolomide Capsule. This adds up to a 28-day treatment cycle.

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

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

How to take Temozolomide Capsule

Take your prescribed dose of Temozolomide Capsule 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 eat breakfast. Swallow the capsule(s) whole with a glass of water. Do not open, crush or chew the capsules. 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
Temozolomide 5 mg hard capsules	green
Temozolomide 20 mg hard capsules	yellow
Temozolomide 100 mg hard capsules	pink
Temozolomide 140 mg hard capsules	blue
Temozolomide 180 mg hard capsules	orange

TEMOTERO 20
(Temozolomide Capsules 20 mg)



Hetero

Temozolomide 250 mg hard capsules	white
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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 Temozolomide Capsule 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.

If you take more Temozolomide Capsule than you should

If you accidentally take more Temozolomide capsules than you were told to, contact your doctor, pharmacist or nurse immediately.

If you forget to take Temozolomide Capsule

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

4. POSSIBLE SIDE EFFECTS

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

Contact your doctor **immediately** if you have any of the following:

- a severe allergic (hypersensitive) reaction (hives, wheezing or other breathing difficulty),
- uncontrolled bleeding,
- seizures (convulsions),
- fever,
- severe headache that does not go away.

Temozolomide capsule treatment can cause a reduction in certain kinds of blood cells. This may cause you to have increased bruising or bleeding, anaemia (a shortage of red blood cells), fever, and reduced resistance to infections. The reduction in blood cell counts is usually short-lived. In some cases, it may be prolonged and may lead to a very severe form of anaemia (aplastic anaemia).

TEMOTERO 20
(Temozolomide Capsules 20 mg)



Your doctor will monitor your blood regularly for any changes, and will decide if any specific treatment is needed. In some cases, your Temozolomide capsule dose will be reduced or treatment stopped.

Side effects from clinical studies:

Temozolomide capsule in combination treatment with radiotherapy in newly-diagnosed glioblastoma

Patients receiving Temozolomide capsule in combination with radiotherapy may experience different side effects than patients taking Temozolomide capsule alone. The following side effects may occur, and may require medical attention.

Very common (may affect more than 1 in 10 people): loss of appetite, headache, constipation (difficulty passing stools), nausea (feeling sick in your stomach), vomiting, rash, hair loss, tiredness.

Common (may affect up to 1 in 10 people): oral infections, wound infection, reduced number of blood cells (neutropenia, thrombocytopenia, lymphopenia, leukopenia), increased sugar in the blood, loss of weight, change in mental status or alertness, anxiety/depression, sleepiness, difficulty speaking, impaired balance, dizziness, confusion, forgetfulness, difficulty concentrating, inability to fall asleep or stay asleep, tingling sensation, bruising, shaking, abnormal or blurry vision, double vision, hearing impairment, shortness of breath, cough, blood clot in the legs, fluid retention, swollen legs, diarrhoea, stomach or abdominal pain, heartburn, upset stomach, difficulty swallowing, dry mouth, skin irritation or redness, dry skin, itching, muscle weakness, painful joints, muscle aches and pains, frequent urination, difficulty with holding your urine, allergic reaction, fever, radiation injury, face swelling, pain, abnormal taste, abnormal liver function tests.

Uncommon (may affect up to 1 in 100 people): flu-like symptoms, red spots under the skin, low potassium level in the blood, weight gain, mood swings, hallucination and memory impairment, partial paralysis, impaired coordination, impaired sensations, partial loss of vision, dry or painful eyes, deafness, infection of the middle ear, ringing in the ears, earache, palpitations (when you can feel your heart beat), blood clot in the lung, high blood pressure, pneumonia, inflammation of your sinuses, bronchitis, a cold or the flu, swollen stomach, difficulty controlling your bowel movements, haemorrhoids, peeling skin, increased skin sensitivity to sunlight, change in skin colour, increased sweating, muscle damage, back pain, difficulty in urinating, vaginal bleeding,

TEMOTERO 20
(Temozolomide Capsules 20 mg)



sexual impotence, absent or heavy menstrual periods, vaginal irritation, breast pain, hot flushes, shivering, discolouration of your tongue, change in your sense of smell, thirst, tooth disorder.

Temozolomide capsule monotherapy in recurrent or progressive glioma

The following side effects may occur, and may require medical attention.

Very common (may affect more than 1 in 10 people): reduced number of blood cells (neutropenia or lymphopenia, thrombocytopenia), loss of appetite, headache, vomiting, nausea (feeling sick in your stomach), constipation (difficulty passing stools).

Common (may affect up to 1 in 10 people): loss of weight, tiredness, dizziness, tingling sensation, shortness of breath, diarrhoea, abdominal pain, upset stomach, rash, itching, hair loss, fever, weakness, shivering, feeling unwell, pain, change in taste.

Uncommon (may affect up to 1 in 100 people): reduced blood cell counts (pancytopenia, anaemia, leukopenia).

Rare (may affect up to 1 in 1,000 people): cough, infections including pneumonia.

Very rare (may affect up to 1 in 10,000 people): skin redness, urticaria (hives), skin eruption, allergic reactions.

Other side effects:

Very rare cases of severe rash with skin swelling, including on the palms of the hands and soles of the feet, or painful reddening of the skin and/or blisters on the body or in the mouth have been observed. Tell your doctor **immediately** if this occurs.

Very rare cases of lung side effects have been observed with Temozolomide capsule. Patients usually present with shortness of breath and cough. Tell your doctor if you notice any of these symptoms.

In very rare cases, patients taking Temozolomide capsule and medicines like it may have a small risk of developing secondary cancers, including leukaemia.

There have been cases of hepatic side effects including elevations of liver enzymes, increased bilirubin, problems with bile flow (cholestasis) and hepatitis. Injury to the liver, including fatal liver failure has been reported.

Reporting of side effects

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 can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TEMOZOLOMIDE CAPSULE

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

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.

Bottle presentation

Do not store above 30 °C.

Store in the original bottle in order to protect from moisture.

Keep the bottle tightly closed.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Temozolomide capsules 100 mg contains

The active substance is Temozolomide. Each hard gelatin capsule contains Temozolomide 100 mg.

The other ingredients are

Capsule content:

Lactose anhydrous Ph.Eur (Supertab 21AN), Sodium starch glycolate Ph.Eur (Explotab Low pH), L(+)-Tartaric acid Powder Ph.Eur (Emprove), Hydrophobic Silica, colloidal anhydrous Ph.Eur (Aerosil R 972 Pharma) and Stearic acid Ph.Eur (Speziol L2 SM GF Pharma)

Capsule shell:

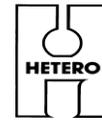
EHG capsule Opaque pink cap and opaque white body, size 1 hard gelatin capsules imprinted with “15” on cap and “H” on Body.

What Temozolomide capsules 100 mg looks like and contents of the pack

Temozolomide capsules 100 mg are Opaque pink cap and opaque white body, size 1 hard gelatin capsules imprinted with “15” on cap and “H” on Body, filled with off white to pale pink granular powder.

Temozolomide capsules 100 mg available in Container pack (Glass bottle):

TEMOTERO 20
(Temozolomide Capsules 20 mg)



Hetero

Container pack (Glass bottle): 5's count

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
Hyderabad-500 018
Andhra Pradesh.

Country: INDIA

Manufacturer:

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