

TEMOZOLOMIDE ALPHAPHARM

Temozolomide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Temozolomide Alphapharm. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Temozolomide Alphapharm against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Temozolomide Alphapharm is used for

Temozolomide Alphapharm is used to treat patients with brain tumours. Temozolomide Alphapharm is also used to treat adult patients with advanced metastatic malignant melanoma.

Your doctor, however, may prescribe Temozolomide Alphapharm for another purpose.

This medicine belongs to a group of medicines called cytotoxic or chemotherapy medicines.

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

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

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

Temozolomide Alphapharm 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).

Before you take Temozolomide Alphapharm

When you must not take it

Do not take Temozolomide Alphapharm if you have an allergy to:

- any medicine containing temozolomide or dacarbazine (DTIC)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

Do not take this medicine if you or your partner are pregnant or intend to become pregnant.

Temozolomide Alphapharm may cause birth defects if either the male or female is using Temozolomide Alphapharm at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before starting Temozolomide Alphapharm. Both male and female patients and their partners should each use some kind of birth control while taking Temozolomide Alphapharm. Male patients whose partners are already pregnant should use a condom to minimise exposure of the unborn baby to Temozolomide Alphapharm in the sperm.

Do not breast-feed if you are taking this medicine.

Do not take this medicine if you have a very low level of white blood cells, red blood cells or platelets.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you vomit frequently.

Your doctor may give you medicine to control the vomiting.

- you are anaemic or have blood clotting problems.
- you have liver or kidney problems.
- have viruses such as cytomegalovirus and hepatitis B.

Tell your doctor if you intend to have children.

Temozolomide Alphapharm may cause infertility in men.

If you have not told your doctor about any of the above, tell them before you start taking Temozolomide Alphapharm.

Taking other medicines

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

These medicines may be affected by Temozolomide Alphapharm or may affect how well it works. These include:

- other medicines used to treat cancer
- other treatment that may lower your immune system
- valproic acid, used to treat epilepsy and bipolar disorder.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. Your doctor will advise you.

How to take Temozolomide Alphapharm

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

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

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

If you are taking Temozolomide Alphapharm 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 Temozolomide Alphapharm 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 Temozolomide Alphapharm 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 Temozolomide Alphapharm capsules once daily for the first five days ("dosing days") of each cycle, followed by 23 days without Temozolomide Alphapharm; 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 Temozolomide Alphapharm. Before each new treatment cycle begins, your blood will be tested to determine if the Temozolomide Alphapharm dose needs to be adjusted.

If you are taking only Temozolomide Alphapharm (patients treated for recurrent brain tumour):

Take the dose the doctor has prescribed once a day for five days.

Depending on your response to Temozolomide Alphapharm, 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 it

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

Temozolomide Alphapharm comes in different strength capsules (shown on the outer label in mg). Each strength is a different colour. Depending on the dose of Temozolomide Alphapharm 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 of each strength (include 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 reinstruction before beginning the treatment cycle. Errors in how you take this medicine may have serious health consequences.

Swallow the capsules whole with a glass of water. Do not open or chew the capsules.

When to take it

Take Temozolomide Alphapharm without food at least one hour before a meal.

It is good practice to take Temozolomide Alphapharm 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 it

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

If you forget to take it

If you miss a dose, 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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 - Australia or 0800 764 766 - New Zealand)) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Temozolomide Alphapharm. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Temozolomide Alphapharm

Things you must do

If you are about to be started on any new medicine, remind your doctor, dentist and pharmacist that you are taking Temozolomide Alphapharm.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor if you feel sick or vomit while being treated with Temozolomide Alphapharm.

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 Temozolomide Alphapharm.

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 Temozolomide Alphapharm.

If you or your partner becomes pregnant while you are being treated with Temozolomide Alphapharm, 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 Temozolomide Alphapharm at the appropriate times to get the best effects from your treatment.

Things you must 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 use Temozolomide Alphapharm to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Temozolomide Alphapharm affects you.

As with other medicines, Temozolomide Alphapharm may make some people feel tired.

If this occurs do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Temozolomide Alphapharm.

Like other medicines that treat cancer, Temozolomide Alphapharm 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea, vomiting, feeling unwell
- tiredness, sleepiness
- constipation
- headache
- loss of appetite or weight
- diarrhoea
- fever or high temperature
- rash, hair loss, itching
- dizziness, weakness
- general body pain
- stomach pain, indigestion

- different taste sensation
- difficulty swallowing
- mouth ulcers
- coughing
- sleeplessness
- difficulty concentrating
- losing balance
- swelling of the face, mouth, legs
- hearing loss
- high blood sugar

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- shortness of breath
- tingling or numbness in hands or feet
- nausea, tiredness, dark urine and yellowing of the skin associated with hepatotoxicity
- bruising, bleeding or being unusually pale or tired

This could be caused by a low level of platelets or red blood cells in the blood.

This could be sign of an infection caused by a low level of white blood cells in the blood.

- symptoms such as fever, headache, personality change, seizures and/or vomiting which could be associated with a brain infection caused by a herpes virus
- new or recurring cytomegalovirus infection and return of hepatitis B
- symptoms of diabetes, such as passing large amounts of urine and constant thirst
- shivering that is associated with chills and fever
- development of red or purple spots under the skin

These last two side effects of Temozolomide Alphapharm may take some time to occur. Therefore, even after you have finished your treatment with Temozolomide Alphapharm, you should tell your doctor immediately if you notice these side effects.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Temozolomide Alphapharm

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Temozolomide Alphapharm or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

The 5 mg capsules are light green opaque, marked with black imprint “TMZ 5 mg”.

The 20 mg capsules are rich yellow marked with black imprint “TMZ 20 mg”.

The 100 mg capsules are flesh coloured, marked with black imprint “TMZ 100 mg”.

The 140 mg capsules are powder blue marked with black imprint “TMZ 140 mg”.

The 180 mg* capsules are orange marked with black imprint “TMZ 180 mg”.

The 250 mg capsules are buff coloured marked with black imprint “TMZ 250 mg”.

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

Ingredients

Active ingredient:

Temozolomide

Inactive ingredients:

- Lactose (in the 5 mg and 20 mg capsules only)
- sodium starch glycollate
- stearic acid
- tartaric acid
- microcrystalline cellulose
- colloidal anhydrous silica.

The capsule shells also contain the following ingredients:

- gelatin
- titanium dioxide
- water
- Opacode Monogramming Ink S-1-277002

- Indigo Carmine (Temozolomide Alphapharm 5 mg and 140 mg)
- Iron Oxide Yellow (Temozolomide Alphapharm 5 mg, 20 mg and 250 mg)
- Iron Oxide Red (Temozolomide Alphapharm 100 mg and 250 mg)
- Iron oxide black (Temozolomide Alphapharm 250 mg)
- Sunset Yellow FCF (Temozolomide Alphapharm 180 mg)
- Allura Red AC (Temozolomide Alphapharm 180 mg)

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

Sponsor

Southern Cross Pharma Pty Ltd

Suite 5/118 Church St

Hawthorn VIC 3122

Distributor

Temozolomide Alphapharm is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

This leaflet was prepared in March 2020.

5 mg capsule AUST R 192687

20 mg capsule AUST R 192678

100 mg capsule AUST R 192684

140 mg capsule AUST R 192680

180 mg capsule AUST R 192692

250 mg capsule AUST R 192681

*The 180mg capsules are not marketed.

Temozolomide Alphapharm_cmi\0320/14