

APO-Temozolomide

Contains the active ingredient temozolomide

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Temozolomide. It contains the active ingredient temozolomide.

It is used to treat:

- patients with certain types of brain tumours called glioblastoma multiforme and anaplastic astrocytoma
- adult patients with advanced metastatic malignant melanoma.

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

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

How it works

Temozolomide 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.

There is no evidence that this medicine is addictive.

Use in children

Temozolomide is 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 this medicine

When you must not take it

Do not take this medicine if:

- **You or your partner are pregnant or intend to become pregnant.**
Temozolomide may cause birth defects if either the male or female is using this medicine at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before

starting this medicine. Both male and female patients and their partners should each use some kind of birth control while taking this medicine. Male patients whose partners are already pregnant should use a condom to minimise exposure of the unborn baby to temozolomide in the sperm.

- **You are breastfeeding.**
It is not known whether temozolomide passes into human breast milk. Animal studies showed retarded development in offspring exposed to temozolomide.
- **You have a very low level of white blood cells, red blood cells or platelets.**
- **You are hypersensitive to, or have had an allergic reaction to, temozolomide, dacarbazine (DTIC) or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include: 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; fainting; or hay fever-like symptoms.
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have, or have had, any medical conditions, especially the following:
 - anaemia or blood clotting problems
 - liver or kidney problems
 - tendency to vomit frequently or experience nausea
 - viruses such as cytomegalovirus and hepatitis B.
3. You intend to have children.
Temozolomide may cause infertility in men.
4. You are planning to have surgery or an anaesthetic.
5. You are currently receiving or are planning to receive dental treatment.
6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with temozolomide. These include:

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

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with temozolomide.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

You may be given other medications to take before or after this medicine to help stop nausea.

Newly diagnosed glioblastoma multiforme (in combination with radiotherapy):

Concomitant Phase

Your doctor will start you on a dose of temozolomide every day for 42 days (up to 49 days if needed due to radiotherapy interruption). Your treatment will then be interrupted for 4 weeks to give your body a chance to recover.

Adjuvant Phase

In the next phase, there are up to 6 treatment cycles. Each treatment cycle lasts 28 days. You will take your new dose of temozolomide once daily for the first 5 days of each cycle, followed by 23 days without temozolomide. After day 28, the next cycle will begin, in which you will again take temozolomide once daily for 5 days followed by 23 days without temozolomide. Before each new treatment cycle begins, your blood will be tested to determine if the temozolomide dose needs to be adjusted.

Recurrent glioblastoma multiforme or anaplastic astrocytoma:

Take the dose the doctor has prescribed once a day for 5 days.

Depending on your response to temozolomide, a new treatment cycle will begin each 28 days. You will then again take temozolomide once daily for 5 days.

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

Metastatic malignant melanoma:

Take the dose the doctor has prescribed once a day for 5 days.

Depending on your response to temozolomide, a new treatment cycle will begin each 28 days. You will then again take temozolomide once daily for 5 days.

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

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

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

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.

If you are confused or unsure about how to take your dose, call your doctor for instruction before beginning the treatment cycle. Errors in how you take this medicine may have serious health consequences.

When to take it

Take this medicine without food at least one hour before a meal.

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

If vomiting occurs after you take this medicine, do not take another dose that day.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

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 take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you or your partner are pregnant or become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may make some people feel tired.

If this occurs do not drive.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking temozolomide or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- nausea, vomiting, feeling unwell
- tiredness, sleepiness
- constipation
- headache
- loss of appetite or weight
- diarrhoea
- fever or high temperature
- hair loss, itching
- dizziness, weakness
- general body pain
- stomach pain, indigestion
- different taste sensation
- mouth ulcers
- coughing
- sleeplessness.

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

These may be serious side effects and you may need medical attention:

- frequent urination, unquenchable thirst
- shortness of breath
- tingling or numbness in hands or feet
- 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.
- 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.
- development of red or purple spots under the skin.

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

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to temozolomide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Temozolomide looks like

5 mg capsules:

Light green opaque, size 4, marked with black imprint "TMZ 5 mg".

20 mg capsules:

Rich yellow opaque, size 1, marked with black imprint "TMZ 20 mg".

100 mg capsules:

Flesh opaque, size 1, marked with black imprint "TMZ 100 mg".

140 mg capsules:

Powder blue opaque, size 1, marked with black imprint "TMZ 140 mg".

180 mg capsules:

Medium orange opaque, size 1, marked with black imprint "TMZ 180 mg".

250 mg capsules:

Buff opaque, size 0, marked with black imprint "TMZ 250 mg".

Available in bottles of 5 capsules

Not all strengths may be available.

Ingredients

Each capsule contains 5 mg, 20 mg, 100 mg, 140 mg, 180 mg or 250 mg of temozolomide as the active ingredient.

It also contains the following inactive ingredients:

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

Temozolomide capsule shells contain:

- gelatin
- water
- titanium dioxide
- iron oxide yellow (5 mg, 20 mg and 250 mg capsules only)
- indigo carmine (5 mg and 140mg capsules only)
- iron oxide red (100 mg and 250mg capsules only)
- iron oxide black (100 mg and 250 mg capsules only)
- sunset yellow FCF (180 mg capsules only)
- allura red AC (180 mg capsules only).

Capsule printing ink is Opacode monogramming ink S-1-277002 BLACK.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Temozolomide 5 mg capsules: AUST R 231523

APO-Temozolomide 20 mg capsules: AUST R 231524

APO-Temozolomide 100 mg capsules: AUST R 231527

APO-Temozolomide 140 mg capsules: AUST R 231528

APO-Temozolomide 180 mg capsules: AUST R 231525

APO-Temozolomide 250 mg capsules: AUST R 231526

Sponsor

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