

APO-Temozolomide

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.

1. Why am I using APO-Temozolomide?

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

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

2. What should I know before I use APO-Temozolomide?

Do not use if you have ever had an allergic reaction to APO-Temozolomide 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 APO-Temozolomide?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Temozolomide 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 APO-Temozolomide?

- Your doctor has worked out the exact dose of APO-Temozolomide 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 APO-Temozolomide?](#) in the full CMI.

5. What should I know while using APO-Temozolomide?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-Temozolomide.• Tell your doctor if you feel sick or vomit while being treated with APO-Temozolomide
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APO-Temozolomide affects you.• As with other medicines, APO-Temozolomide may make some people feel tired. If this occurs do not drive.
Looking after your medicine	<ul style="list-style-type: none">• Keep your APO-Temozolomide capsules in the bottle pack until it is time to use them.• Keep APO-Temozolomide 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 APO-Temozolomide?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, APO-Temozolomide 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 APO-Temozolomide. When you get APO-Temozolomide, 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.

APO-Temozolomide

Active ingredient: *temozolomide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Temozolomide. **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 APO-Temozolomide.**

Where to find information in this leaflet:

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

1. Why am I using APO-Temozolomide?

APO-Temozolomide contains the active ingredient temozolomide.

APO-Temozolomide belongs to a group of medicines called cytotoxic or chemotherapy medicines.

APO-Temozolomide works by killing cancer cells and stopping cancer cells from growing and multiplying.

APO-Temozolomide is used to treat patients with brain tumours.

APO-Temozolomide is also used to treat adult patients with advanced metastatic malignant melanoma.

Your doctor, however, may prescribe APO-Temozolomide for another purpose.

Use in children

APO-Temozolomide 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 APO-Temozolomide has been prescribed for you.

2. What should I know before I use APO-Temozolomide?

Warnings

Do not use APO-Temozolomide if: You are allergic to APO-Temozolomide [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.

You are anaemic or have blood clotting problems.

You intend to have children.

APO-Temozolomide may cause infertility in men.

You have liver or kidney problems.

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

You 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.

APO-Temozolomide may cause birth defects if either the male or female is using APO-Temozolomide at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before starting APO-Temozolomide. Both male and female patients and their partners should each use some kind of birth control while taking APO-Temozolomide 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 APO-Temozolomide 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 APO-Temozolomide or may affect how well APO-Temozolomide 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 APO-Temozolomide.

4. How do I use APO-Temozolomide?

How much to take

Your doctor has worked out the exact dose of APO-Temozolomide for you according to your individual needs. You may be given other medication to take before or after APO-Temozolomide to help stop nausea.

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

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

Take the dose the doctor has prescribed once a day for five days. Depending on your response to APO-Temozolomide, 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 APO-Temozolomide

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

APO-Temozolomide comes in different strength capsules (shown on the outer label in mg). Each strength is a different colour. Depending on the dose of APO-Temozolomide 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 APO-Temozolomide

Take APO-Temozolomide 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 APO-Temozolomide 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 APO-Temozolomide

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

If you forget to use APO-Temozolomide

APO-Temozolomide 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 APO-Temozolomide

If you think that you have used too much APO-Temozolomide, 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 APO-Temozolomide?

Things you should do

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with APO-Temozolomide.

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

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 APO-Temozolomide.

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 APO-Temozolomide.

If you or your partner becomes pregnant while you are being treated with APO-Temozolomide, 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 APO-Temozolomide 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 APO-Temozolomide.

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 APO-Temozolomide to anyone else, even if they have the same condition as you.
- Do not use APO-Temozolomide 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 APO-Temozolomide affects you.

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

Looking after your medicine

- Keep your APO-Temozolomide capsules in the bottle pack until it is time to use them.
- Keep APO-Temozolomide 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 window sills.

Keep it where young children cannot reach it.

When to discard your medicine

- Do not use APO-Temozolomide after the expiry date printed on the pack.
- Do not use APO-Temozolomide 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, APO-Temozolomide 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">• 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• mouth ulcers• coughing• sleeplessness	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shortness of breath• tingling or numbness in hands or feet• bruising, bleeding or being unusually pale or tired <p>This could be caused by a low level of platelets or red blood cells in the blood.</p>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

<ul style="list-style-type: none"> new or recurring cytomegalovirus infection and return of hepatitis B symptoms of diabetes include passing large amount of urine and constant thirst symptoms such as fever, headache, personality change, seizures, and/or vomiting which could be associated with a brain infection caused by herpes virus. 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 <p>These last two side effects of APO-Temozolomide may take some time to occur. Therefore, even after you have finished your treatment with APO-Temozolomide, you should tell your doctor immediately if you notice these side effects.</p>	these serious side effects.
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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. 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 APO-Temozolomide contains

Active ingredient (main ingredient)	Temozolomide
Other ingredients (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 purified water titanium dioxide iron oxide yellow (5 mg, 20 mg and 250 mg capsules only) indigo carmine (5 mg and 140 mg capsules only) iron oxide red (100 mg and 250 mg 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.
Potential allergens	Contains lactose (5 mg and 20 mg capsules only) Contains trace amounts of sulfites

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

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

What APO-Temozolomide looks like

5 mg capsules:

Light green opaque, size 4, marked with black imprint "TMZ 5 mg". AUST R 231523.

20 mg capsules:

Rich yellow opaque, size 1, marked with black imprint "TMZ 20 mg". AUST R 231524.

100 mg capsules:

Flesh opaque, size 1, marked with black imprint "TMZ 100 mg". AUST R 231527.

140 mg capsules:

Powder blue opaque, size 1, marked with black imprint "TMZ 140 mg". AUST R 231528.

180 mg capsules:

Medium orange opaque, size 1, marked with black imprint "TMZ 180 mg". AUST R 231525.

250 mg capsules:

Buff opaque, size 0, marked with black imprint "TMZ 250 mg". AUST R 231526.

Available in bottles of 5 capsules.

Not all strengths may be available.

Who distributes APO-Temozolomide

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

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