

Temozolomide Juno

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 Temozolomide Juno?

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

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

2. What should I know before I use Temozolomide Juno?

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

3. What if I am taking other medicines?

Some medicines may interfere with temozolomide and affect how it works.

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 Temozolomide Juno?

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

5. What should I know while using Temozolomide Juno?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Temozolomide Juno.• Tell your doctor if you feel sick or vomit while being treated with Temozolomide Juno.
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 temozolomide affects you.• As with other medicines, temozolomide may make some people feel tired. If this occurs do not drive.
Looking after your medicine	<ul style="list-style-type: none">• Store Temozolomide Juno in a cool, dry place where the temperature stays below 25°C.• Keep your capsules in the original sachets or bottles until it is time to take them.• Follow the instructions on the pack on how to take care of your medicine properly.

For more information, see Section [5. What should I know while using Temozolomide Juno?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, temozolomide can cause side effects. Your doctor will discuss these with you and will explain the risks and benefits of using this medicine.

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.

Temozolomide Juno

Active ingredient(s): *temozolomide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Temozolomide Juno. **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 Temozolomide Juno.**

Where to find information in this leaflet:

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

1. Why am I using Temozolomide Juno?

Temozolomide Juno contains the active ingredient temozolomide. Temozolomide belongs to a group of medicines called cytotoxic or chemotherapy medicines.

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

Temozolomide is used to treat patients with brain tumors. It is also used to treat adult patients with advanced metastatic malignant melanoma.

Your doctor, however, may prescribe temozolomide for another purpose.

Use in children

Temozolomide Juno capsules are used to treat children 3 years of age 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 Temozolomide Juno has been prescribed for you.

2. What should I know before I use Temozolomide Juno?

Warnings

Do not use Temozolomide Juno if:

- You are allergic to temozolomide, dacarbazine (DTIC) or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the

face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath. Always check the ingredients to make sure you can use this medicine.

- You are pregnant or you or your partner intend to become pregnant** (see pregnancy information below).
- You are breastfeeding** (see breastfeeding information below).
- You have a very low level of white blood cells, red blood cells or platelets (myelosuppression).**

Check with your doctor if you:

- Have allergies to any other medicines, foods, preservatives or dyes.**
- Intend to have children.** Temozolomide may cause infertility in men.
- Vomit frequently.** Your doctor may give you medicine to control the vomiting.
- Are anaemic or have blood clotting problems.**
- Have liver or kidney problems.** Temozolomide could cause hepatitis B to become active again, which can be fatal in some cases.
- 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 and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Temozolomide may cause birth defects if either the male or female is using it at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before starting temozolomide. Both male and female patients and their partners should each use some kind of birth control while taking 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 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.

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 temozolomide, or may affect how well it works. These include other medicines used to treat cancer or any other treatments that may affect 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 temozolomide.

4. How do I use Temozolomide Juno?

How much to take

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

If you are taking Temozolomide Juno 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 Juno 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.

You will then start the next phase of treatment ("adjuvant phase"). and your Temozolomide Juno 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 Juno capsules once daily for the first five days ("dosing days") of each cycle, followed by 23 days without Temozolomide Juno; 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 Juno.

Before each new treatment cycle begins, your blood will be tested to determine if the Temozolomide Juno dose needs to be adjusted.

If you are taking Temozolomide Juno alone (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 Juno, 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 Temozolomide Juno

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.

Temozolomide Juno comes in different strength capsules (shown on the outer label in 'mg'). Each strength is a different colour. Depending on the dose of Temozolomide Juno 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 re-instruction before beginning the treatment cycle.

Errors in how you take this medicine may have serious health consequences.

When to take Temozolomide Juno

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

It is good practice to take it 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 for

Keep taking Temozolomide Juno exactly as your doctor recommends.

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

If you forget to use Temozolomide Juno

Temozolomide Juno 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 Temozolomide Juno

If you think that you have used too much 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 Temozolomide Juno?

Things you should do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Temozolomide Juno.

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

Your doctor may give you another medicine to help with this.

Tell your doctor if you become unusually pale or tired, get blood clotting problems or frequent infections while being treated with Temozolomide Juno.

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 Juno.

Tell your doctor immediately if you or your partner becomes pregnant while taking Temozolomide Juno.

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 Juno 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 Temozolomide Juno.

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 use Temozolomide Juno to treat any other conditions unless your doctor tells you to.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how temozolomide affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make some side effects worse.

Looking after your medicine

- Keep your capsules in the original sachets or bottles until it is time to take them.
- Keep your capsules 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 (as relevant)

- Do not use Temozolomide Juno after the expiry date printed on the pack.
- Do not use Temozolomide Juno 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.

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. This could be caused by a low level of platelets or red blood cells in the blood. • new or recurring cytomegalovirus infection and return of hepatitis B • symptoms of diabetes, such as 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 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.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 Temozolomide Juno contains

Active ingredient (main ingredient)	Temozolomide
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose • colloidal anhydrous silica • sodium starch glycollate • tartaric acid • stearic acid • gelatin • purified water • titanium dioxide • indigo carmine CI73015 (5 mg and 140 mg capsules only) • iron oxide yellow (5 mg, 20 mg and 180 mg capsules only) • iron oxide red (100 mg and 180 mg capsules only) • TekPrint SW-9008 black ink, (ARTG 2328).
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Do not take this medicine if you are allergic to any of these ingredients.

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

What Temozolomide Juno looks like

Temozolomide Juno capsules come in the following strengths:

- 5 mg– green and white capsule printed with “TMZ” and “5” in black
- 20 mg– yellow and white capsule printed with “TMZ” and “20” in black
- 100 mg– pink and white capsule printed with “TMZ” and “100” in black
- 140 mg– blue and white capsule printed with “TMZ” and “140” in black
- 180 mg – maroon and white capsule printed with “TMZ” and “180” in black
- 250 mg– white capsule printed with “TMZ” and “250” in black.

Sachet Pack: Each sachet contains 1 capsule. There are 5 sachets or 20 sachets in a pack.

Bottle Pack: Each bottle contains 5 capsules or 20 capsules.

Australian registration numbers (sachets):

- Temozolomide Juno 5 - AUST R206042
- Temozolomide Juno 20 - AUST R206043
- Temozolomide Juno 100 - AUSTR 206044
- Temozolomide Juno 140 - AUSTR 206215
- Temozolomide Juno 180 - AUSTR 206045
- Temozolomide Juno 250 - AUSTR 206046.

Australian registration numbers (bottles):

- Temozolomide Juno 5 - AUST R354885
- Temozolomide Juno 20 - AUST R354886
- Temozolomide Juno 100 - AUSTR 354887
- Temozolomide Juno 140 - AUSTR 354890
- Temozolomide Juno 180 - AUSTR 354888
- Temozolomide Juno 250 - AUSTR 354889.

Who distributes Temozolomide Juno

Juno Pharmaceuticals Pty Ltd
42 Kelso Street,
Cremorne,
VIC – 3121

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