

ORION TEMOZOLOMIDE CAPSULES

(Temozolomide 5mg, 20mg, 100mg, 140mg, 180mg and 250mg)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Orion Temozolomide Capsules. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor or pharmacist has weighed the benefits against the risks of you taking this medicine.

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

Keep this leaflet with the medicine.

You may want to read it again.

What Orion Temozolomide Capsules is used for

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

Your doctor, however, may prescribe Orion Temozolomide Capsules for another purpose.

Ask your doctor if you have any questions about why Orion Temozolomide Capsules has been prescribed for you.

Orion Temozolomide Capsules belongs to a group of medicines called cytotoxic or chemotherapy medicines.

Orion Temozolomide Capsules works by killing cancer cells from growing and multiplying.

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

Use in children

Orion 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).

Before you take Orion Temozolomide Capsules

When you must not take it

Do not take Orion Temozolomide Capsules if:

- you are allergic to temozolomide, dacarbazine (DTIC) or any of the ingredients listed at the end of this leaflet.** 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, difficulty breathing, wheezing, or a tight feeling in your chest.

- you or your partner are pregnant or intend to become pregnant.**

Orion Temozolomide Capsules may cause birth defects if either male or female is using Orion Temozolomide Capsules at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before starting Orion Temozolomide Capsules. 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**
- you have a very low level of white blood cells, red blood cells or platelets.**

Do not use Orion Temozolomide Capsules after the expiry date printed on the bottle.

Do not use Orion Temozolomide Capsules if the packaging shows signs of tampering.

Before you start to take it

You must tell 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.**
Orion Temozolomide Capsules may cause infertility in men.
- you have liver or kidney problems.**
- you have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes

Taking other medicines

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

Some medicines may be affected by Orion Temozolomide Capsules or may affect how well Orion Temozolomide Capsules 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.

How to take Orion Temozolomide Capsules

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How much to take

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

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

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

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

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

Depending on your response to Orion Temozolomide Capsules, 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

Orion Temozolomide Capsules come in different capsule strengths (shown on the outer label in mg). Each strength is a different colour. Depending on the dose of Orion Temozolomide Capsules 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 of each strength you need to take. 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.

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

When to take it

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

It is good practice to take Orion Temozolomide Capsules 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 Poisons Information Centre (Phone 13 11 26 for Australia or 0800 764 766 for New Zealand) for advice, if you think you or anyone else may have taken too much Orion Temozolomide Capsules. Do this even if there are no signs of discomfort or poisoning.

While you are taking Orion Temozolomide Capsules

Things you must do

Tell any of the doctors, dentists, and pharmacists who are treating you that you are being treated with Orion Temozolomide Capsules.

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

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 Orion Temozolomide Capsules.

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 Orion Temozolomide Capsules.

If you or your partner becomes pregnant while you are being treated with Orion Temozolomide Capsules, 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 Orion Temozolomide Capsules 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 Orion Temozolomide Capsules.

Store Orion Temozolomide Capsules out of the reach of children.

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 give Orion Temozolomide Capsules to anyone else, even if they have the same condition as you.

Do not use Orion Temozolomide Capsules to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery, until you know how

Orion Temozolomide Capsules affects you.

As with other medicines, Orion Temozolomide Capsules 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 Orion Temozolomide Capsules.

Like other medicines that treat cancer, Orion Temozolomide Capsules 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.

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 sensations
- mouth ulcers
- coughing
- sleeplessness

These are the more common side effects of Orion Temozolomide Capsules.

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

- 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 may be serious side effects.

You may need medical attention.

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

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Orion Temozolomide Capsules

Keep your Orion Temozolomide Capsules in a bottle until it is time to use them.

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

Do not leave it in the car or on windowsills.

Keep it where children cannot reach it.

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

Disposal

Return any unused medicine to your pharmacist.

Product description

What it looks like

- **Orion Temozolomide 5mg Capsules:** White opaque capsules, with two stripes in green ink on the cap and with "T 5mg" in green ink on the body.
- **Orion Temozolomide 20mg Capsules:** White opaque capsule, with two stripes in orange ink on the cap and with "T 20mg" in orange ink on the body.
- **Orion Temozolomide 100mg Capsules:** White opaque capsule, with two stripes in pink ink on the cap and with "T 100mg" in pink ink on the body.
- **Orion Temozolomide 140mg Capsules:** White opaque capsule, with two stripes in blue ink on the cap and with "T 140mg" in blue ink on the body.
- **Orion Temozolomide 180mg Capsules:** White opaque capsule, with two stripes in red ink on the cap and with "T 180mg" in red ink on the body.
- **Orion Temozolomide 250mg Capsules:** White opaque capsule, with two stripes in black ink on the cap and with "T 250mg" in black ink on the body.

Each glass bottle contains 5 or 20 capsules.

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

Ingredients

Active ingredient:

- temozolomide

Inactive ingredients:

- anhydrous lactose
- sodium starch glycollate
- stearic acid
- tartaric acid
- colloidal anhydrous silica

The capsule shells also contain the following ingredients:

- gelatine
- titanium dioxide
- TekPrint SB-4020 Green Ink [ARTG No. 2652] (Orion Temozolomide 5mg Capsules)
- TekPrint SB-2008 Orange Ink [ARTG No. 107473] (Orion Temozolomide 20mg Capsules)
- Pink TekPrint SW-1105 [ARTG 3325] (Orion Temozolomide 100mg Capsules)
- TekPrint SB-6018 Blue Ink [ARTG 2653] (Orion Temozolomide 140mg Capsules)
- TekPrint SW-1102 Red Ink [ARTG 107015] (Orion 180mg Temozolomide Capsules)

- OPACODE monogramming ink S- S-1-277002 black [ARTG 107581] (Orion Temozolomide 250mg Capsules)

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

Sponsor

Orion Laboratories Pty Ltd

25 - 29 Delawney Street
Balcatta WA 6021

Orion Temozolomide 5mg Capsules: AUST R
179874

Orion Temozolomide 20mg Capsules: AUST R
179872

Orion Temozolomide 100mg Capsules: AUST R
179869

Orion Temozolomide 140mg Capsules: AUST R
179870

Orion Temozolomide 180mg Capsules: AUST R
179871

Orion Temozolomide 250mg Capsules: AUST R
179873

This leaflet was prepared in: October 2011

Date of last amendment: June 2013

ACC03031P:2