
Consumer Medicine Information

Temozolomide Devatis

Temozolomide Capsules

5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg

What is in this leaflet

Please read this leaflet carefully before you start using Temozolomide Devatis.

This leaflet answers some common questions about Temozolomide Devatis. 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 Devatis 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 Devatis is used for

Temozolomide Devatis is used for the treatment of brain tumours. Temozolomide Devatis is also used to treat adult patients with advanced metastatic malignant melanoma.

Your doctor, however, may have prescribed Temozolomide Devatis for another reason.

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

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

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

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

Use in children

Temozolomide Devatis 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 Devatis

Warnings

Do not use Temozolomide Devatis if: **You are allergic to Temozolomide Devatis (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.

Temozolomide Devatis may cause infertility in men.

You have liver or kidney problems.

Temozolomide Devatis 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 Side Effects](#)

Pregnancy

Check with your doctor if you are pregnant or intend to become pregnant.

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

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 Devatis or may affect how well Temozolomide Devatis 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 Temozolomide Devatis.

How to take Temozolomide Devatis

How much to take

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

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

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

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

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

If you are taking only Temozolomide Devatis (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 Devatis 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.

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

All patients

Temozolomide Devatis capsules come in different strength capsules (shown on the outer label in mg). Each strength is a different colour. Depending on the dose of Temozolomide Devatis 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 it

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

It is good practice to take Temozolomide Devatis 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 are not sure what to do, ask your doctor or pharmacist.

While you are taking Temozolomide Devatis

Things you must do

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

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

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 Devatis.

If you or your partner becomes pregnant while you are being treated with Temozolomide Devatis 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 Temozolomide Devatis 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 Temozolomide Devatis.

Store Temozolomide Devatis 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 Temozolomide Devatis to anyone else, even if they have the same condition as you.

Do not use Temozolomide Devatis 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 Temozolomide Devatis capsules affect you.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Temozolomide Devatis.

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

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, Temozolomide Devatis 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
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<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> <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 temozolomide may take some time to occur. Therefore, even after you have finished your treatment with Temozolomide Devatis, 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>
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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 <https://pophealth.my.site.com/carmreportnz/s/>. 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.

After taking Temozolomide Devatis

Storage

Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the pack, they may not keep well.

The capsules should be stored at or below 25°C. **Store in the original bottle in order to protect from moisture.**

Keep the bottle tightly closed.

Do not store Temozolomide Devatis in the bathroom or near a sink. Do not leave it in the car or on a windowsill. 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 they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Temozolomide Devatis 5 mg:

Opaque light green cap and opaque white body with 5 mg print on it, filled with white to light pink powder; hard gelatin capsule size “3”.

Temozolomide Devatis 20 mg:

Opaque rich yellow cap and opaque white body with 20 mg print on it, filled with white to light pink powder; hard gelatin capsule size “2”.

Temozolomide Devatis 100 mg:

Opaque flesh cap and opaque white body with 100 mg print on it, filled with white to light pink powder; hard gelatin capsules size “1”.

Temozolomide Devatis 140 mg:

Transparent light blue cap and opaque white body with 140 mg print on it, filled with white to light pink powder; hard gelatin capsule size “0”.

Temozolomide Devatis 180 mg:

Opaque Swedish orange cap and opaque white body with 180 mg print on it, filled with white to light pink powder; hard gelatin capsule size “0”.

Temozolomide Devatis 250 mg:

Opaque white cap and opaque white body with 250 mg print on it, filled white to with light pink powder; hard gelatin capsules size “0”.

Temozolomide Devatis 5 mg, 20 mg, 100 mg, 140 mg, 180 mg & 250 mg are supplied in amber coloured glass bottles of 5 and 20 capsules closed with child-resistant white opaque closures.

Not all strengths or pack sizes may be marketed.

Ingredients

Active ingredient(s):

- Temozolomide

Inactive ingredients:

- Lactose
- Sodium starch glycolate type A
- Colloidal anhydrous silica
- Tartaric acid

- Stearic acid

Temozolomide Devatis capsule shells contain:

- Gelatin
- Titanium Dioxide (E171)
- Printing ink (contains shellac glaze 45% in ethanol, iron oxide black (E172), N-butyl alcohol, purified water, propylene glycol (E1520), dehydrated ethanol, isopropyl alcohol, ammonium hydroxide 28% (E517))

Temozolomide Devatis 5 mg capsule shells also contain yellow iron oxide (E172) and indigotine - FD&C Blue 2 (E132).

Temozolomide Devatis 20 mg capsule shells also contain yellow iron oxide (E172).

Temozolomide Devatis 100 mg capsule shells also contain red iron oxide (E172).

Temozolomide Devatis 140 mg capsule shells also contain indigotine-FD&C Blue 2 (E132).

Temozolomide Devatis 180 mg capsule shells also contain red iron oxide (E172).

Temozolomide Devatis capsules are gluten free.

Sponsor details

Temozolomide Devatis is supplied in New Zealand by:

DEVATIS LIMITED

Findex, 173 Spey Street, Invercargill 9810, New Zealand

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www.devatis.nz

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