

Temaccord

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 Temaccord.

This leaflet answers some common questions about Temaccord. 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 Temaccord 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 Temaccord is used for

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

Your doctor, however, may have prescribed Temaccord for another reason.

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

Temaccord belongs to a group of medicines called cytotoxic or chemotherapy medicines.

Temaccord 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

Temaccord 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 Temaccord

When you must not take it

Do not take Temaccord if you have an allergy to:

- any medicine containing temozolomide or dacarbazine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not take Temaccord if you have a very low level of white blood cells, red blood cells or platelets.

Do not take this medicine if you are pregnant or intending to become pregnant.

Temaccord may cause birth defects if either the male or female is taking Temaccord at the time of conception or during pregnancy. Therefore, female patients must have a negative pregnancy test before starting Temaccord capsules. Both

male and female patients and their partners should each use some kind of birth control while taking Temaccord.

Male patients whose partners are already pregnant should use a condom to minimise exposure of the unborn baby to temozolomide in the sperm.

Do not breastfeed if you are taking this medicine.

It is not known whether Temaccord passes into breastmilk.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tempering.

If you are not sure whether you should start using Temaccord, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you vomit frequently.** Your doctor may give you medicine to control the vomiting.
- 2. you have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 3. you are anaemic or have blood clotting problems.**
- 4. you have liver or kidney problems.**
Temaccord could cause hepatitis B to become active again, which can be fatal in some cases.
- 5. you are intend to have children.**
Temaccord may cause infertility in men.

If you have not told your doctor about any of the above, tell them before you start using Temaccord.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Temaccord.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Temaccord.

Some medicines may be affected by Temaccord or may affect how well Temaccord 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 Temaccord

How much to take

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

You may be given other medication to take before or after Temaccord 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 Temaccord 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 Temaccord 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 Temaccord 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 Temaccord capsules once daily for the first five days ("dosing days") of each cycle, followed by 23 days without Temaccord; 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 Temaccord. Before each new treatment cycle begins, your blood will be tested to determine if the Temaccord dose needs to be adjusted.

If you are taking only Temaccord (patients treated for recurrent brain tumour):

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

Depending on your response to Temaccord 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

Temaccord capsules come in different strength capsules (shown on the outer label in mg). Each strength is a different colour. Depending on the dose of Temaccord 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 Temaccord capsules without food at least one hour before a meal.

It is good practice to take Temaccord 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 Temaccord

Things you must do

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

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

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 Temaccord.

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 Temaccord.

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

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

Do not use Temaccord 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 Temaccord capsules affect you.

As with other medicines, Temaccord 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 Temaccord.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Temaccord.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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 sensation
- mouth ulcers
- coughing
- sleeplessness

These are the more common side effects of Temaccord.

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

- 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 Temaccord capsules may take some time to occur. Therefore, even after you have finished your treatment with Temaccord, you should tell your doctor immediately if you notice these side effects.

Tell your doctor if you notice any other effects.

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

After taking Temaccord

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.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store Temaccord 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

Temaccord 5 mg
Green/White hard gelatin capsules, size '3' imprinted 'TMZ' on cap and '5' on body, containing white to light pink powder.

Temaccord 20 mg
Yellow/White hard gelatin capsules, size '5' imprinted 'TMZ' on cap and '20' on body, containing white to light pink powder.

Temaccord 100 mg
Pink/White hard gelatin capsules, size '3' imprinted 'TMZ' on cap and '100' on body, containing white to light pink powder.

Temaccord 140 mg
Transparent Blue/White hard gelatin capsules,
size '1' imprinted 'TMZ' on cap and '140' on body,
containing white to light pink powder.

Temaccord 180 mg
Maroon /White hard gelatin capsules, size '1'
imprinted 'TMZ' on cap and '180' on body,
containing white to light pink powder.

Temaccord 250 mg
White/White hard gelatin capsules, size '0'
imprinted 'TMZ' on cap and '250' on body,
containing white to light pink powder.

Ingredients

Active ingredient(s):

- Temozolamide

Inactive ingredients:

- Anhydrous lactose
- Sodium starch glycollate
- Stearic acid
- Tartaric acid
- Colloidal anhydrous silica

Temaccord capsule shells contain:

- Titanium Dioxide (E171)
- Gelatin
- TekPrint SW-9008 Black Ink.

Temaccord 5 mg capsule shells also contain Iron Oxide Yellow (E172) and FD&C Blue 2 (E132).
Temaccord 20 mg capsule shells also contain Iron Oxide Yellow (E172).
Temaccord 100 mg capsule shells also contain Iron Oxide Red (E172).
Temaccord 140 mg capsule shells also contain FD&C Blue 2 (E132).
Temaccord 180 mg capsule shells also contain Iron Oxide Red (E172) and Iron Oxide Yellow (E172).

Temaccord capsules are gluten free.

Sponsor details

Temaccord is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

Date of preparation

23 September 2019
(based on data sheet dated 23 September 2019)