

## Consumer Medicine Information

### TEMACCORD CAPSULES 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg

*Temozolomide*

#### What is in this leaflet

This leaflet answers some common questions about Temaccord 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 risks and benefits. Your doctor has weighed the risks of you taking Temaccord capsules against the benefits they expect it will have for you.

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

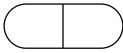

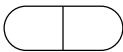
**Keep this leaflet with the medicine.** You may need to read it again.

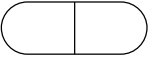
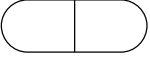

#### Product Description

##### *What TEMACCORD CAPSULES look like*

Temaccord capsules are presented in six strengths. They are 5 mg, 20 mg, 100 mg, 140 mg, 180 mg and 250 mg

**Please note that the 5 mg capsule is larger than the 20 mg capsule.**

Strength (mg/cap)	Visual	Product Description	Capsule Size	Capsule Dimensions (mm)
5 mg		Green/White hard gelatin capsules, size '3' imprinted 'TMZ' on cap and '5' on body, containing white to light pink powder.	Size 3	approx 15.8 ± 0.4
20 mg		Yellow/White hard gelatin capsules, size '5' imprinted 'TMZ' on cap and '20' on body, containing white to light pink powder.	Size 5	approx 11.4 ± 0.4
100 mg		Pink/White hard gelatin capsules, size '3' imprinted 'TMZ' on cap and '100' on body, containing white to light pink	Size 3	approx 15.8 ± 0.4

		powder.		
<b>140 mg</b>		Transparent Blue/White hard gelatin capsules, size '1' imprinted 'TMZ' on cap and '140' on body, containing white to light pink powder.	<b>Size 1</b>	approx 19.3± 0.4
<b>180 mg</b>		Maroon /White hard gelatin capsules, size '1' imprinted 'TMZ' on cap and '180' on body, containing white to light pink powder.	<b>Size 1</b>	approx 19.3± 0.4
<b>250 mg</b>		White/White hard gelatin capsules, size '0' imprinted 'TMZ' on cap and '250' on body, containing white to light pink powder.	<b>Size 0</b>	approx 21.4 ± 0.4

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

Temaccord capsules are presented in Amber glass bottles with child resistant polypropylene closures.

---

## Ingredients

---

### Active ingredients

- Temozolomide

### Inactive ingredients:

The inactive ingredients are anhydrous lactose, sodium starch glycollate Type A, stearic acid, tartaric acid and colloidal anhydrous silica in a gelatin capsule shell.

Temaccord capsule shells contains Titanium Dioxide (E171) and Gelatin, and are imprinted with 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 250 mg capsule shells also contain Sodium lauryl sulphate

Temaccord capsules do not contain sucrose, gluten, tartrazine or other azo dyes.

Temaccord is gluten free.

---

## What Temaccord capsules are used for

---

Temaccord capsules are used to treat patients with brain tumours.

Temaccord capsules are also used to treat adult patients with advanced metastatic malignant melanoma.

Your doctor, however, may prescribe Temaccord capsules for another purpose.

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

Temaccord capsules belong to a group of medicines called cytotoxic or chemotherapy medicines.

The temozolomide in Temaccord capsules works by killing cancer cells and stopping cancer cells from growing and multiplying.

This medicine is only available 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 capsules

---

### *When you must not take it*

#### 1. Do not take Temaccord capsules if

- you have an allergy to any medicine containing temozolomide, dacarbazine (DTIC) or any of the ingredients listed under the section "Ingredients" 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, wheezing, difficulty breathing or a tight feeling in your chest

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

Temaccord capsules may cause birth defects if either the male or female is using 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 capsules. Male patients whose partners are already pregnant should use a condom to minimise exposure of the unborn baby to temozolomide in the sperm.

**3. you are breastfeeding.**

**4. you have a very low level of white blood cells, red blood cells or platelets.**

**Do not use Temaccord capsules after the expiry date printed on the bottle.**

**Do not use Temaccord capsules if the packaging shows signs of tampering.**

***Before you start to take it***

**You must tell your doctor if**

1. **you vomit frequently.** Your doctor may give you medicine to control the vomiting.
2. **you are anaemic or have blood clotting problems.**
3. **you intend to have children.** Temaccord capsules may cause infertility in men.
4. **you have liver or kidney problems.**
5. **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 Temaccord capsules or may affect how well 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.

---

## How to take Temaccord 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 Temaccord for you according to your individual needs.

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

### **If you are taking Temaccord 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 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 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 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.

**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**

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

***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 take too much (overdose)***

Immediately telephone your doctor or the Poisons Information Centre - the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 or go to Accident and Emergency (Casualty) at your nearest hospital, if you think that you or anyone else may have taken too many Temaccord capsules . Do this even if there are no signs of discomfort or poisoning.

---

**While you are taking Temaccord capsules**

---

***Things you must do***

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

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

**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 capsules.**

**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 capsules to anyone else, even if they have the same condition as you.**

**Do not use Temaccord 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 Temaccord capsules affect you.**

As with other medicines, Temaccord 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 Temaccord capsules.**

Like other medicines that treat cancer, Temaccord 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 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:**

- 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 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 Temaccord capsules**

---

### **Storage**

**Keep your Temaccord capsules in the bottle until it is time to use them.**

---

---

**Keep Temaccord capsules in a cool dry place where the temperature stays below 25°C**

**Do not leave it in the car or on window sills.**

**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***

Return any unused medicine to your pharmacist.

---

## **Further Information**

---

Temaccord Capsules are a Prescription Only Medicine.

---

## **Distributor**

---

Douglas Pharmaceuticals Ltd  
Central Park Drive  
Lincoln  
Auckland 0610  
New Zealand  
pH: +64 9 835 0660

---

## **Date of preparation**

---

***22 August 2011***