

## **For the Patient: PROTOCOL SMAVTMZ**

Other Names: Palliative Therapy for Malignant Melanoma with Brain Metastases Using Temozolomide

**SM** = Melanoma

**AV** = Advanced

**TMZ** = Temozolomide

### **ABOUT THIS MEDICATION**

#### **What is this drug used for?**

- Temozolomide is a drug given alone or with radiation therapy to treat certain cancers of the brain or central nervous system. It is a capsule that is taken by mouth.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to dacarbazine (DTIC®) before taking temozolomide.

#### **How does this drug work?**

- Temozolomide kills cancer cells by preventing their normal cell division and growth.

### **INTENDED BENEFITS**

- This therapy is being given to destroy and/or limit the growth of cancer cells in your body. It may improve your current symptoms, and delay or prevent the onset of new ones.
- It may take several treatments before your doctor can determine whether or not this treatment is helping.

### **TREATMENT SUMMARY**

#### **How is this drug given?**

- Temozolomide is a capsule taken by mouth usually as a single dose, once daily at bedtime. You may be given capsules of more than one strength to make the right dose. The BCCA Pharmacy may package these capsules in a blister pack to make it easier for you to take.
- Temozolomide is taken for five days in a row, followed by a 23 day rest period. This 28 day period (5 days of temozolomide + 23 days of rest) is called a “cycle”. The cycle is repeated up to 8 times, depending on your response, but may be changed based on how the chemotherapy affects you.

The following calendar outlines your treatment plan for each cycle.

Weeks	Treatment Plan
1	Temozolomide once daily at bedtime x 5 days (day 1 – 5) No treatment on day 6 and 7
2	No treatment
3	No treatment
4	No treatment

### What will happen when I get my drug?

- Your very first appointment for this treatment will take longer than other appointments because a pharmacist will be reviewing the possible side effects of your chemotherapy plan and how to manage them. It is a good idea to bring someone with you to your first appointment for this treatment.
- A blood test is done each cycle, the day before or the first day of each treatment. The dose and timing of your chemotherapy may be changed based on your blood counts and/or other side effects.
- At the discretion of the attending oncologist, you may be given a prescription for anti-nausea drugs which can be filled at your local community pharmacy. This medication is to be taken 30-45 minutes before the temozolomide to lessen the side effects of treatment. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.
- Temozolomide may cause **sterility** in men and **menopause** in women. If you plan to have children, discuss this with your doctor before being treated with temozolomide.
- Temozolomide may damage sperm and may harm the baby if used during pregnancy. Men and women are advised to use an effective method of **birth control** during and for 6 months after treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- **Tell** doctors or dentists that you are being treated with temozolomide before you receive any treatment from them.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

### Are there any risks?

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

SERIOUS SIDE EFFECTS	How common is it?	MANAGEMENT
Your <b>white blood cells</b> will decrease 3-4 weeks after your treatment. They usually return to normal within 2 weeks. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, <b>you are at greater risk of having an infection.</b>	Uncommon	To help prevent infection: <ul style="list-style-type: none"><li>• Wash your hands often and always after using the bathroom.</li><li>• Take care of your skin and mouth.</li><li>• Avoid crowds and people who are sick.</li><li>• Stop taking temozolomide and call your doctor <b>immediately</b> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, sore throat or burning when you pass urine.</li></ul>
Your <b>platelets</b> may decrease 3-4 weeks after your treatment. They usually return to normal within 2 weeks. Platelets help to make your blood clot when you hurt yourself. <b>You may bruise or bleed more easily than usual.</b>	Uncommon	To help prevent bleeding problems: <ul style="list-style-type: none"><li>• Try not to bruise, cut, or burn yourself.</li><li>• Clean your nose by blowing gently. Do not pick your nose.</li><li>• Avoid constipation.</li><li>• Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene.</li><li>• Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</li><li>• Do not stop taking any medication that has been prescribed by your doctor (e.g., <b>ASA for your heart</b>).</li><li>• For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable.</li></ul>

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
<b>Nausea and vomiting</b> may occur.	Very Common	<p>You may be given a prescription for anti-nausea drug(s) to take before your temozolomide dose. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> <li>• Taking your dose on an empty stomach, at least one hour before or after you eat, or at bedtime may help to reduce nausea.</li> <li>• Drink plenty of liquids.</li> <li>• Eat and drink often in small amounts.</li> <li>• Try the ideas in <i>Food Choices to Control Nausea</i>.</li> </ul>
<b>Constipation or diarrhea</b> may occur.	Uncommon	<p>To help constipation:</p> <ul style="list-style-type: none"> <li>• Exercise if you can.</li> <li>• Drink plenty of fluids (8 cups a day).</li> <li>• Try ideas in <i>Suggestions for Dealing with Constipation</i>.</li> </ul> <p>To help diarrhea:</p> <ul style="list-style-type: none"> <li>• Drink plenty of liquids.</li> <li>• Eat and drink often in small amounts.</li> <li>• Avoid high fibre foods as outlined in <i>Coping with Diarrhea</i></li> <li>• <b>Note:</b> If lactose in milk usually gives you diarrhea, the lactose in the capsule may be causing your diarrhea. Take LACTAID® just before your temozolomide dose.</li> </ul>
<b>Headache</b> may occur.	Uncommon	<ul style="list-style-type: none"> <li>• Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.</li> </ul>
<b>Sugar control</b> may be affected in diabetics.	Rare	<ul style="list-style-type: none"> <li>• Check your blood sugar regularly if you are diabetic.</li> </ul>

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
<b>Tiredness</b> and lack of energy may occur.	Rare	<ul style="list-style-type: none"> <li>• Do not drive a car or operate machinery if you are feeling tired.</li> <li>• Try the ideas in <i>Your bank of energy savings: How people with cancer can handle fatigue</i>.</li> </ul>
<b>Hair loss</b> is rare with temozolomide. Your hair will grow back once you stop treatment with temozolomide. Colour and texture may change.	Rare	<ul style="list-style-type: none"> <li>• Use a gentle shampoo and soft brush.</li> <li>• Care should be taken with use of hair spray, bleaches, dyes and perms.</li> </ul>

## **INSTRUCTIONS FOR THE PATIENT**

### **How should I store this drug?**

- **Store** temozolomide capsules out of the reach of children, at room temperature, away from heat, light and moisture.

### **How should I use this drug?**

- You may be given capsules of more than one strength to make the right dose. Make sure you understand the directions.
- Temozolomide may be taken with food or on an empty stomach with a glass of water or juice. However, it is best to take your dose at the same time each day relative to when you eat (ie, try not to take it with a meal one day, and on an empty stomach the next day). Taking your dose on an empty stomach (at least one hour before or after you eat) or at bedtime may help reduce nausea.
- Swallow the capsules whole. Do not open or chew the capsules.
- If you **vomit** after taking temozolomide, do not take a second dose. Call your doctor during office hours for advice.
- If you **miss a dose** of temozolomide, take it as soon as you can if it is within 12 hours of the missed dose. If it is over 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times. Call your doctor during office hours to ask about making up the missed dose.

### **What other drugs can interact with Temozolomide?**

- Other drugs such as valproic acid (DEPAKENE®) may **interact** with temozolomide. Tell your doctor if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start taking any new drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of temozolomide. If you are taking dexamethasone or drugs to prevent seizures, discuss the safety of alcohol with your doctor.

**THE FOLLOWING INFORMATION IS VERY IMPORTANT**

**STOP TAKING TEMOZOLOMIDE AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:**

- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer); chills; cough; sore throat; pain or burning when you pass urine.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain or shortness of breath.

**CONTINUE TAKING TEMOZOLOMIDE AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IF YOU HAVE:**

- **Seizures** or **loss of consciousness**.
- Sudden onset of **severe muscle weakness** or **paralysis**.

**SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:**

- Signs of **anemia** such as unusual tiredness or weakness.

**CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:**

- Uncontrolled nausea, vomiting, constipation or diarrhea.
- Pain in your stomach or abdomen.
- Headache not controlled with acetaminophen.
- For diabetics: uncontrolled blood sugars.
- Easy bruising.
- Skin rash or itching.
- Memory loss (amnesia)

**If you experience symptoms or changes in your body that have not been described above but worry you, or in any symptoms are severe, contact:**

\_\_\_\_\_ at telephone number: \_\_\_\_\_