



For the Patient: UGIAVTZCAP

Other Names: Palliative therapy of metastatic neuroendocrine cancer of the pancreas, using Temozolomide and Capecitabine

U = Undesignated

GI = GastroIntestinal

AV = Advanced

TZCAP = Temozolomide, **Ca**pecitabine

ABOUT THIS MEDICATION

What are these drugs used for?

- Temozolomide and capecitabine are drugs given to treat neuroendocrine tumours of the pancreas.

How do these drugs work?

- Temozolomide and capecitabine work by interfering with dividing cells and preventing an increase in the number of cancer cells.

INTENDED BENEFITS

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

TREATMENT SUMMARY

How are these drugs given?

- Capecitabine is a tablet that you take by mouth. It is usually taken **twice a day**, about 12 hours apart, with equal numbers of tablets taken at each dose. It is started on day one (1) of treatment and is given for 14 days in a row.
- Temozolomide is a capsule that you take by mouth. It is usually taken **once a day**. It is started on day ten (10) of treatment and is given for five days in a row.
- When you have finished the medication, you will be given a rest period. The medications will then be started again 28 days following the first day of your treatment. This 28 day period of time is called a “cycle”.
- The cycle is repeated as long as you are benefiting from treatment and not having too many side effects, as determined by your oncologist.

The calendar on the following page outlines how the medications are given each 28 days cycle.

C Y C L E 1	DATE	TREATMENT PLAN
		▶ Week 1 → Capecitabine orally a.m. and p.m. with food for 7 days
		▶ Week 2 → Capecitabine orally a.m. and p.m. with food for 7 days → Temozolomide orally once daily on an empty stomach for 5 days, from day 10 to 14.
		▶ Week 3 → no treatment
		▶ Week 4 → no treatment

C Y C L E 2	DATE	TREATMENT PLAN
		▶ Week 1 → Capecitabine orally a.m. and p.m. with food for 7 days
		▶ Week 2 → Capecitabine orally a.m. and p.m. with food for 7 days → Temozolomide orally once daily on an empty stomach for 5 days, from day 10 to 14.
		▶ Week 3 → no treatment
		▶ Week 4 → no treatment

The cycles are repeated as long as you are benefiting from treatment and not having too many side effects.

What will happen when I get my drugs?

- A **blood test** is done each cycle, on or before the first day of each five day treatment cycle. The dose and timing of your chemotherapy may be changed based on your blood counts and / or other side effects.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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 drugs in your treatment plan.

Your doctor will review the risks of treatment and possible side effects with you before starting treatment. The pharmacist will review possible side effects of the drugs and how to manage those side effects with you on the day you receive your first treatment.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Nausea and vomiting may occur.	<p>You may be given a prescription for an anti-nausea drug(s) to take before your chemotherapy treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> • Taking your dose on an empty stomach, at least one hour before or after you eat, may help to reduce nausea. • Drink plenty of liquids. • Eat and drink often in small amounts. • Try the ideas in <i>Food Choice to Control Nausea*</i>.
Hand-foot skin reaction may occur very commonly during capecitabine treatment. The palms of your hands and soles of your feet may tingle, become red, numb, painful, or swollen. Skin may also become dry or itchy. You may not be able to do your normal daily activities if blisters, severe pain or ulcers occur.	<ul style="list-style-type: none"> • Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity. • Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. • Apply lanolin-containing creams (eg. BAG BALM®, UDDERLY SMOOTH®) to hands and feet liberally and often. • Tell your cancer doctor at the next visit if you have any signs of hand-foot skin reaction. • Stop taking capecitabine and call your cancer doctor if the skin reaction is painful, as your dose may need to be changed. Taking a lower dose does not affect the usefulness of capecitabine.
Diarrhea may occur during your treatment.	<p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of fluids • Eat and drink often in small amounts • Eat low fibre foods and avoid high fibre foods as outline in <i>Coping with Diarrhea*</i>.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Sore mouth may occur commonly during treatment. Mouth sores can occur on the tongue, the sides of the mouth or in the throat. Mouth sores or bleeding gums can lead to an infection.</p>	<ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Make a mouthwash with ½ teaspoon baking soda or salt in 1 cup warm water and rinse several times a day. • Try soft, bland foods like puddings, milkshakes and cream soups. • Avoid spicy, crunchy or acidic food, and very hot or cold foods. • Try ideas in <i>Easy to Chew, Easy to Swallow Food Ideas*</i>.
<p>Your white blood cells 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, you are at greater risk of having an infection.</p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Take care of your skin and mouth. • Avoid crowds and people who are sick. • Call your doctor immediately at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.
<p>Your platelets 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. You may bruise or bleed more easily than usual.</p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. <p>Some medications such as ASA (e.g. ASPIRIN®) or ibuprofen (e.g. ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g. ASA for your heart). <p>For minor pain, try acetaminophen (e.g. TYLENOL®) first, but occasional use of ibuprofen may be acceptable.</p>

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Headache may occur.	<ul style="list-style-type: none"> Take acetaminophen (e.g. TYLENOL®) to decrease or stop headache.
Sugar control may be affected in diabetics.	<ul style="list-style-type: none"> Check your blood sugar regularly if you are diabetic.
Tiredness and lack of energy may occur.	<ul style="list-style-type: none"> Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Your bank of energy savings: How people with cancer can handle fatigue.</i>*
Your skin may sunburn easily.	<p>To help prevent sunburn:</p> <ul style="list-style-type: none"> Avoid direct sunlight. Wear a hat, long sleeves and long pants or skirt outside on sunny days. Apply a sun block lotion with an SPF (sun protection factor) of at least 15.
Hair loss is rare with both temozolomide and capecitabine. If it does occur, your hair will grow back once you stop treatment. Colour and texture may change.	<ul style="list-style-type: none"> Use a gentle shampoo and soft brush. Care should be taken with use of hair spray, bleaches, dyes and perms.

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever had an unusual or **allergic reaction** to fluorouracil (5FU, ADRUCIL®) or to dacarbazine (DTIC®) before taking capecitabine or temozolomide.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of capecitabine or temozolomide.
- If you **vomit** after taking capecitabine or temozolomide, do not take another dose. Call your doctor during office hours for advice.
- **Store** capecitabine tablets and temozolomide capsules out of the reach of children, at room temperature and away from heat, light and moisture.
- Both capecitabine and temozolomide contain **lactose**.
- Temozolomide may cause **sterility** in men and **menopause** in women. Men taking temozolomide are advised not to father a child during or for 6 months after treatment. If you plan to have children, discuss this with your doctor before being treated with temozolomide.
- Capecitabine and temozolomide may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with capecitabine and temozolomide. 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 capecitabine and temozolomide before you receive any treatment from them.

Capecitabine

- Capecitabine is taken by mouth **twice a day**, about 12 hours apart, with equal numbers of tablets taken at each dose. You may be given tablets of more than one strength to make the right dose. Capecitabine should be taken within 30 minutes following the end of a meal (breakfast and dinner) with a glass of water. It is usually **given for 14 days, followed by a 7 day break**.
- If you **miss a dose of capecitabine**, take it as soon as you can if it is within 6 hours of the missed dose. If it is over 6 hours since the missed dose, skip the missed dose and go back to the usual dosing time. Call your doctor during office hours to ask about making up the missed dose.
- Sometimes capecitabine treatment has to be **stopped for a short time** because of side effects. When you **restart** capecitabine treatment, do not make up for the missed dose; instead, take as directed by your cancer doctor and finish the treatment on the same day as originally planned. For example, if you stop on day 3 of your 14-day treatment course and then restart at a later day, you would still take the last dose on day 14. You may be told to take a different dose and you may have extra tablets left over. Return the extra tablets to the clinic at your next visit. Taking a lower dose does not affect the usefulness of capecitabine.

Temozolomide

- Temozolomide is taken by mouth **once a day**, on an empty stomach (30 – 60 minutes before a meal or 2 hours after a meal). You may be given capsule of more than one strength to make the right dose.
- You will be given a prescription for anti-nausea medication to take before your temozolomide dose.
- Unless your doctor gives you other directions, take each dose in the morning.
- Swallow the capsule whole. Do not open or chew the capsules.

- If you **miss a dose** of capecitabine or 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 usually dosing times. Call your doctor during office hours to ask about making up the missed dose.

Medication Interactions

- Other drugs such as warfarin (COUMADIN®), phenytoin (DILANTIN®), and fosphenytoin (CEREBYX®) may interact with capecitabine. 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 FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING CAPECITABINE AND 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; 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 **heart problems** such as fast or uneven heartbeat, pain or pressure in the chest, jaw or arm, shortness of breath or difficulty breathing.
- 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.
- **Seizures, memory loss** (amnesia) or **loss of consciousness**.
- **Severe muscle weakness** or **paralysis**.
- **Uncontrolled nausea, vomiting or diarrhea**.

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

- **Painful hand-foot skin reaction** such as painful redness, peeling, tingling, numbness, swelling or blistering of the palms of your hands and/or bottoms of your feet. If there is a delay in seeing your doctor, stop taking your capecitabine tablets until you are seen or have discussed with your doctor
- **Diarrhea** with four stools a day more than usual, or diarrhea during the night.
- **Nausea** that causes you to eat a lot less than usual or **vomiting** more than 2 times in 24 hours.
- **Painful redness, swelling or sores on your lips, tongue, mouth or throat**.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Signs of **anemia** such as unusual tiredness or weakness.
- **Severe abdominal or stomach cramping or pain**.
- Signs of **heart problems** such as swelling of feet or lower legs

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

- Painless hand-foot skin reaction such as redness, peeling, tingling, numbness, swelling or blistering of the palms of your hands and/or bottoms of your feet,
- Painless redness, swelling or sores on your lips, tongue, mouth or throat.
- Pain in your stomach or abdomen.
- Headache not controlled by acetaminophen.
- For diabetics: uncontrolled blood sugars
- Easy bruising or bleeding
- Loss of appetite or constipation.
- Skin rash or itching.
- Changes in fingernails or toenails.
- Heartburn; mild to moderate abdominal or stomach pain.
- Watery, irritated eyes.

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

_____ at telephone number: _____