

For the Patient: GIGAVCCT

Other Names: Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Adenocarcinoma Using Cisplatin, Capecitabine and Trastuzumab

GI = GastroIntestinal

GAV = Gastric (stomach), Advanced

CCT = Cisplatin, Capecitabine, Trastuzumab

ABOUT THIS MEDICATION

What are these drugs used for?

- Cisplatin, capecitabine and trastuzumab are drugs used to treat cancer of the stomach, stomach-esophagus junction, or esophagus.

How do these drugs work?

- Cisplatin and capecitabine work by interfering with dividing cells and preventing an increase in the number of cells.
- Trastuzumab helps your immune system to interfere with how cancer cells grow and divide.

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?

- Cisplatin and trastuzumab are given directly into the vein (IV). Capecitabine is a tablet taken by mouth.
- You will receive cisplatin and trastuzumab at the clinic by a chemotherapy nurse on the first day of treatment **for one day only**. You will be given capecitabine tablets to start on the same day. They are to be taken twice a day, everyday for 14 days in a row, followed by a one week or 7 day break.
- This three week or 21-day period of time is called a “cycle”. The cycles are repeated as long as you are benefiting from chemotherapy, and not having too many side effects, as determined by your oncologist.
- Each treatment will take **about 3 hours**. Your first treatment will take longer, as the nurse will review information on the chemotherapy drug with you. The treatment will be followed by an observation time, to ensure that the trastuzumab does not cause any infusion related side effects. If your body does not experience any infusion related side effects, the observation time may be shortened, as determined by your chemotherapy nurse.
- Capecitabine will be given to you by a pharmacist each time you come in for a cisplatin and trastuzumab treatment. You will be given enough tablets so you can take them while at home.

The calendar below shows how the medications are given each 3 week cycle.

C Y C L E	DATE	TREATMENT PLAN
		▶ Week 1 → cisplatin, trastuzumab IV on Day 1 + → Capecitabine orally in the a.m. and p.m. x 7 days.
	1	▶ Week 2 → capecitabine orally in the a.m. and p.m. x 7 days.
		▶ Week 3 → no treatment

C Y C L E	DATE	TREATMENT PLAN
		▶ Week 1 → cisplatin, trastuzumab IV on Day 1 + → capecitabine orally in the a.m. and p.m. x 7 days.
	2	▶ Week 2 → capecitabine orally in the a.m. and p.m. x 7 days.
		▶ Week 3 → no treatment

Treatment is continued 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 treatment cycle. The dose and timing of your chemotherapy may be changed based on your blood counts and/or other side effects
- You will be given **hydration fluid** directly into the vein (IV) before receiving your cisplatin. This helps prevent kidney problems.
- Your doctor may ask you to **drink water** on the morning of your cisplatin treatment (2 – 3 cups). Following your treatment your doctor may ask you to drink plenty of liquids.
- A test to determine how well your **heart** is working, called a “MUGA” scan, will be done at the beginning of treatment.
- You will have been given a prescription for **anti-nausea medication** (to be filled at your regular community pharmacy) that you bring in each time for your cisplatin treatment. Your chemotherapy nurse will tell you when to take the anti-nausea medication. It is easier to prevent nausea than to treat it once it has occurred, so follow directions closely.

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 chemotherapy nurse will review possible side effects of cisplatin and trastuzumab, and how to manage those side effects with you on the day you receive your first treatment. The pharmacist will review how to take the capecitabine and possible side effects with you on the day you first pick up your medication.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Allergic reactions to cisplatin may rarely occur. Signs of an allergic reaction are dizziness, feeling faint, confusion, shortness of breath, and wheezing. This reaction occurs immediately or several hours after receiving cisplatin. This reaction can occur after the first dose or after many doses.</p>	<p>Tell your nurse <i>immediately</i> if this happens while you are receiving the drugs or contact your doctor <i>immediately</i> if this happens after you leave the clinic.</p>
<p>Allergic reactions to trastuzumab may rarely occur. Signs of an allergic reaction may include chills, fever, shivering, nausea, vomiting, headache, dizziness, problems breathing, rash and weakness during the infusion. Reactions are less common with later treatments even if you have a reaction with the first treatment.</p>	<p>Tell your nurse <i>immediately</i> if this happens while you are receiving trastuzumab.</p> <ul style="list-style-type: none"> • Your trastuzumab may be temporarily stopped and then given more slowly when restarted. • You may be given other drugs to treat the reaction. <p>Contact your oncologist <i>immediately</i> if this happens after you leave the clinic.</p>
<p>Cisplatin may burn if it leaks under the skin.</p>	<p>Tell your nurse or doctor <i>immediately</i> if you feel burning, stinging or any other change while the drug is being given.</p>
<p>Nausea and vomiting may occur after your treatment and may last for up to 24 hours. Nausea may last longer for some patients (i.e. delayed nausea and vomiting).</p>	<p>You will 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"> • Drink plenty of liquids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea*</i>. <p>Your doctor may manage delayed nausea and vomiting differently. Be sure to let your doctor know if you experience this.</p>

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Diarrhea may occur.</p>	<p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outline in <i>Food Choices to Help Manage Diarrhea*</i>. <p>If you have an increase of less than 4 stools per day more than normal, or a mild increase in ostomy output, start the following:</p> <ul style="list-style-type: none"> • Loperamide (IMODIUM®) 2 mg, take 2 tablets (4mg) to start, followed by 1 tablet (2 mg) every 4 hours, or after each unformed stool to a maximum of 8 tablets (16 mg) daily, unless otherwise directed by a physician <p>Stop taking capecitabine and call your cancer doctor if you have four stools a day more than usual or diarrhea during the night, or a moderate increase in ostomy output, as your capecitabine dose may need to be changed.</p> <ul style="list-style-type: none"> • Note: if lactose in milk usually gives you diarrhea, the lactose in the capecitabine tablet may be causing your diarrhea. Take LACTAID® tablets just before your dose.
<p>Your white blood cells will decrease during or after your treatment. They usually return to normal after your last treatment. 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 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>Sore mouth may occur 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>Food Ideas to Try with a Sore Mouth*</i>.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Hand-foot skin reaction may occur 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.</p>	<ul style="list-style-type: none"> • Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that cause by heavy activity. • Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. • Apply lanolin-containing creams (e.g. 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 reaction. • Stop taking capecitabine and call your cancer doctor if the skin reaction is painful, as your dose may need to be changes. Taking a lower dose does not affect the usefulness of capecitabine.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Pain or tenderness may occur where the needle was placed.</p>	<ul style="list-style-type: none"> • Apply cool compresses or soak in cool water for 15-20 mins. several times a day.
<p>Fever, chills, and flu-like illness may rarely occur shortly after treatment with trastuzumab. Fever should last no longer than 24 hours.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. • Fever (over 100°F or 38°C by an oral thermometer) which occurs more than a few days after treatment may be a sign of an infection. Report this to your doctor immediately.
<p>Your platelets may decrease during or after your treatment. They will return to normal after your last treatment. 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). • For minor pain, try acetaminophen (e.g. TYLENOL®) first, but occasional use of ibuprofen may be acceptable.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Your skin may sunburn easily.	To help prevent sunburn: <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 30. • Refer to Your Medication Sun Sensitivity and Sunscreens* or the BC Health Guide for more information. • After sun exposure, if you have a severe sunburn or skin reaction such as itching, rash, or swelling, contact your doctor.
You may feel some general pain . Take acetaminophen (e.g. TYLENOL®) to decrease or stop pain.	You may feel some general pain. Take acetaminophen (e.g. TYLENOL®) to decrease or stop pain.
Hair loss is rare with cisplatin and capecitabine and does not occur with trastuzumab . 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 hair spray, bleaches, dyes and perms.

***Please ask your chemotherapy nurse, pharmacist or dietitian for a copy**

Special note:

Heart Problems: Serious heart problems can occur when starting capecitabine. These can rarely be fatal. Problems such as chest pain, heart attack, abnormal heart rhythm, or heart failure can occur. Having a history of heart problems with fluorouracil, a related chemotherapy drug, is a risk factor, as is having a history of prior angina (heart pain) or heart attack. Seek medical attention promptly if you experience feelings of heavy pressure or pain in the chest, trouble breathing, significant worsening leg swelling, or marked lightheadedness. These symptoms can occur within days after starting capecitabine. If your symptoms are severe, you may need to call for emergency help.

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever had an unusual or **allergic reaction** to cisplatin, trastuzumab, capecitabine or fluorouracil.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of cisplatin, capecitabine or trastuzumab.
- Cisplatin may cause **sterility** in men and **menopause** in women. If you plan to have children, discuss this with your doctor before being treated with cisplatin.
- Cisplatin and capecitabine may **damage sperm**. Cisplatin, capecitabine and trastuzumab may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with these drugs. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Tell doctors, dentist and other health professionals that you are being treated with cisplatin, capecitabine and trastuzumab, before you receive any treatment from them.

Capecitabine

- Capecitabine is taken by mouth twice a day, about 10-12 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.
- The tablet contains lactose.
- If you vomit after taking capecitabine, do not take a second dose. Call your doctor during office hours for advice.
- 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. Let your doctor know during office hours if you have missed a 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.
- Store capecitabine tablets out of the reach of children; at room temperature; away from heat, light and moisture.

Other important things to know:

- Cisplatin can cause changes in kidney function. It is important that you are well-hydrated before and after treatment.
- Sometimes, the nerve which allows you to hear can be affected by cisplatin. This could result in you experiencing “tinnitus” (ringing in the ears) or a change in your hearing. Report any of these problems to your doctor and/or nurse.

Medication Interactions

Other drugs may interact with capecitabine, such as phenytoin (DILANTIN®), fosphenytoin (CEREBRYX®) and warfarin (COUMADIN®). Other drugs may interact with cisplatin, such as furosemide (LASIX®), phenytoin (DILANTIN®), pyridoxine, and some antibiotics given by vein (e.g. tobramycin, vancomycin). Other drugs may interact with trastuzumab such as warfarin (COUMADIN®).

Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changes. Check with your doctor or pharmacist before you start taking any new drugs.

THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING CAPECITABINE 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 an **allergic reaction** (rare) soon after a treatment including dizziness, fast heart beat, face swelling or breathing problems.
- Signs of **bleeding problems** such as black, tarry stools, blood in urine, pinpoint red spots on skin, extensive bruising.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of ankles, or fainting.
- Signs of a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- 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 or loss of consciousness** with or without **confusion, headache, or changes in eyesight.**
- **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 the bottoms of your feet.
- **Muscle weakness.**
- Signs of **kidney problems** such as lower back/side pain, swelling of feet or lower legs.
- **Diarrhea** with four stools a day more than usually 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, selling 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.**

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.
- Easy bruising or minor bleeding.
- Heartburn, mild to moderate abdominal or stomach pain.
- Painless redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Redness, swelling, pain or sores where the needle was placed.
- Headache not controlled by acetaminophen.
- Ringing in your ears or hearing problems.
- Aches and pains.
- Skin rash or itching.

- Changes in fingernails or toenails.
- Numbness or tingling in feet or hands or painful leg cramps.
- Watery eyes, eye irritation or changes in eyesight.

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: _____