

For the Patient: GIGAVCFT

Other Names: Palliative treatment of metastatic or inoperable, locally advanced stomach or stomach-esophagus junction cancer using Cisplatin, Infusional Fluorouracil and Trastuzumab

GI = GastroIntestinal
GAV = Gastric (stomach), Advanced
CFT = Cisplatin, Fluorouracil, Trastuzumab

ABOUT THIS MEDICATION

What are these drugs used for?

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

How do these drugs work?

- Fluorouracil and cisplatin 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?

- Fluorouracil, cisplatin and trastuzumab are all given directly into the vein (IV).
- 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 also be given fluorouracil over **120 hours or 5 days**, using a disposable infusion device, called an INFUSOR® or “baby bottle”. The infusion device delivers the fluorouracil slowly and continuously to your body over the 5 day period of time. Please see a copy of “*Your INFUSOR® - A Guide for Patients*”, available through your chemotherapy nurse.
- The infusion device is connected to your veins by either a peripherally inserted central catheter (PICC Line) or a PORT-A-CATH®. If using a PICC line, this is inserted in your upper arm. If using a PORT-A-CATH®, this is inserted under the skin of the chest using local freezing. The insertion would be done before your treatment starts and would be removed once the treatment program is finished.
- The chemotherapy nurse will connect the infusion device to your IV site at the clinic and then you can go home while your treatment is delivered over the 5 days. You may return to the clinic after 5 days for the nurse to disconnect the infusion device, or you will be instructed how to disconnect yourself at home. Some people may be instructed to go to their local hospital to be disconnected, or may have a home care nurse provide this service, if available. You will then have a 16 day rest period.

- 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 4 hours**. This includes the time it takes for the cisplatin and trastuzumab to drip into your body, or what is called an “infusion”. This is then 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. The treatment time also includes a dressing change if you have a PICC line. If you have a PORT-A-CATH®, a dressing change is not needed, so your treatment will take less time. Your first treatment will probably take longer, as the nurse will review information on the chemotherapy drugs and infusion device with you.

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

C Y C L E	DATE	TREATMENT PLAN	
	1		▶ Week 1 → Cisplatin, Trastuzumab IV on Day 1 + Fluorouracil Infusion over 120 hours starting on Day 1
			▶ Week 2 → no treatment
			▶ Week 3 → no treatment

C Y C L E	DATE	TREATMENT PLAN	
	2		▶ Week 1 → Cisplatin, Trastuzumab IV on Day 1 + Fluorouracil Infusion over 120 hours starting on Day 1
			▶ Week 2 → no treatment
			▶ 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 fluids (8 – 12 cups a day).
- 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 fluorouracil, cisplatin and trastuzumab, and how to manage those side effects with you on the day you receive your first treatment.

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>Fluorouracil and cisplatin may burn if either 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>

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<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>
<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 (4 mg) 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>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 <u>immediately</u> 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.

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>Food Ideas to Try with a Sore Mouth*</i>.

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 or headache .	Take acetaminophen (e.g. TYLENOL®) to decrease or stop pain.
Skin rashes may occur.	To help itching: <ul style="list-style-type: none"> • You can use calamine lotion. • If very irritating, call your doctor during office hours. • Otherwise mention it at your next visit.
Loss of appetite may occur with fluorouracil and may persist long after discontinuation of the drug.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
Hair loss is rare with cisplatin but sometimes occurs with fluorouracil. Trastuzumab does not cause hair loss. Your hair will grow back once you stop treatment with fluorouracil. 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 fluorouracil. 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 capecitabine, 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 fluorouracil. 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 fluorouracil, cisplatin or trastuzumab.
- Fluorouracil and 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.
- Fluorouracil and cisplatin may damage sperm. Fluorouracil, cisplatin 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 or other health care professionals that you are being treated with fluorouracil, cisplatin and trastuzumab, before you receive any treatment from them.

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 fluorouracil, 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 changed. Check with your doctor or pharmacist before you start taking any new drugs.

THE FOLLOWING INFORMATION IS VERY IMPORTANT

SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heart beat, face swelling or breathing problems.
- 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, 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.
- Sudden **abdominal pain** or tenderness.
- **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.
- Signs of **anemia** such as unusual tiredness or weakness.
- **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, 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.
- **Severe skin** irritation.

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.
- Uncontrolled loss of appetite.
- Heartburn, mild to moderate abdominal or stomach pain. Redness, swelling, pain, or sores where the needle was placed.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Headache not controlled by acetaminophen.
- Ringing in your ears or hearing problems.
- Dizziness or trouble walking
- Aches and pains.
- Skin rash or itching.
- 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: _____