For the Patient: GIGAVEOF
Palliative therapy for metastatic or locally advanced gastric or or esophagogastric cancer using Epirubicin, Oxaliplatin and Infusional Fluorouracil

GIG = GastroIntestinal, Gastric
AV = Advanced
EOF = Epirubicin, Oxaliplatin, Fluorouracil

ABOUT THIS MEDICATION

What are these drugs used for?
- Epirubicin, oxaliplatin and fluorouracil (5FU) are drugs given to treat metastatic or locally advanced cancer of the stomach or esophagus.

How do these drugs work?
- Epirubicin, oxaliplatin and fluorouracil 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?
- Epirubicin, oxaliplatin and fluorouracil are given directly into the vein (IV).
- You will receive epirubicin and oxaliplatin at the clinic by a chemotherapy nurse on the first day of treatment for one day only. On the first day of treatment, you will also be given the fluorouracil using a disposable infusion device, called an INFUSOR®, which will deliver the fluorouracil over a 7 day period of time. You will receive this infusion device once a week for three weeks in a row. This means you will receive a constant dose of fluorouracil over 21 days, or a three week period of time.
- 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 7 days. You will return to the clinic after 7 days for the nurse to disconnect the infusion device, and connect you to a second 7 day infusion device. You will receive a third infusion device after another 7 days.
• This 21 days or three week period of time is called a “cycle”. The cycle is usually repeated up to 8 cycles as long as you are benefiting from treatment and not having too many side effects, as determined by your oncologist.

• Each treatment will take about 3 hours. This 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.

<table>
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<tr>
<th>CYCLE</th>
<th>DATE</th>
<th>TREATMENT PLAN</th>
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<td>Week 1 ➔ Epirubicin IV and Oxaliplatin IV on Day 1 + Fluorouracil infusion over 7 days starting on day 1</td>
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<td>Week 2 ➔ Fluorouracil infusion over 7 days starting on day 8</td>
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<td>Week 3 ➔ Fluorouracil infusion over 7 days starting on day 15</td>
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Treatment is continued up to 8 cycles 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 weekly – before day 1 of every cycle and before each fluorouracil infusor connection. 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 chemotherapy nurse 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.

<table>
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<tr>
<th>SERIOUS SIDE EFFECTS DURING TREATMENT</th>
<th>MANAGEMENT</th>
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| Tell your nurse if you feel like you have difficulty breathing or swallowing during or immediately after your oxaliplatin infusion. This may occur rarely. | • These symptoms will disappear in a few hours, and may not require treatment.  
• If you have these symptoms with a 2-hour infusion, your next treatment may be given over 6 hours. |
| Allergic reactions may very rarely occur. Signs of an allergic reaction are dizziness, feeling faint, confusion, shortness of breath, and wheezing. This may occur immediately or several hours after receiving the drugs. It can occur after the first dose, or after many doses. | Tell your nurse if this happens while you are receiving the drugs or contact your doctor immediately if this happens after you leave the clinic. |
| Epirubicin, oxaliplatin and fluorouracil burn if any of these drugs leak under the skin. | Tell your nurse or doctor immediately if you feel burning, stinging, or any other change while the drug is being given. |
| Nausea and vomiting may occur after your treatment and may last for 24-48 hours. | You will be given a prescription for antinausea 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.  
• Drink plenty of liquids.  
• Eat and drink often in small amounts.  
• Try the ideas in Practical Tips to Manage Nausea* |
| You may feel tingling or a loss of feeling in your hands, feet, nose, or throat. They may be made worse by exposure to cold. This is very common after oxaliplatin treatment. These problems often disappear after a few hours or days. | • Avoid cold air if possible.  
• Protect yourself from the cold, which can cause or worsen these symptoms. Wear gloves, socks, and something that covers your mouth and nose when outside in cold weather.  
• Do not drink cold beverages or eat cold food for a few days after treatment.  
• If symptoms continue for more than a week, or interfere with how your hands work, talk to your doctor.  
• Try the ideas in Coping With/Preventing Oxaliplatin Cold Dysesthesias* |
### SERIOUS SIDE EFFECTS DURING TREATMENT

<table>
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<tr>
<th>Side Effect</th>
<th>Management</th>
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| **Diarrhea** | may occur during your treatment.  
To help diarrhea:  
• Drink plenty of fluids  
• Eat and drink often in small amounts  
• Eat low fibre foods and avoid high fibre foods as outlined in *Food Choices to Help Manage Diarrhea*  
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:  
• 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 |
| Your **white blood cells** will decrease 1-2 weeks after your treatment.  
They usually return to normal 3 weeks 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. | To help prevent infection:  
• Wash your hands often and always after using the bathroom.  
• Take care of your skin and mouth.  
• Call your doctor immediately at the first sign of an infection such as fever (over 100ºF or 38ºC by an oral thermometer), chills, cough, or burning when you pass urine. |
| **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.** |  
• 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 *Food Ideas to Try with a Sore Mouth* |

### OTHER SIDE EFFECTS DURING TREATMENT

<table>
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<tr>
<th>Side Effect</th>
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| **Pain or tenderness** | may occur where the needle was placed.  
• Apply warm compresses or soak in warm water for 15-20 mins. Several times a day. |
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<td><strong>Fever</strong> may occur shortly after treatment with oxaliplatin. Fever should last no longer than 24 hours.</td>
<td>• Take acetaminophen (e.g. TYLENOL®) every 3-4 hours.</td>
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<td>• Fever which occurs more than 48 hours after treatment maybe the sign of an infection. See “white blood cells” above.</td>
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<td><strong>Your urine may be pink or reddish</strong> for 1 – 2 days after your treatment.</td>
<td>This is expected as epirubicin is red and is passed in your urine.</td>
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<td><strong>Your platelets</strong> may decrease during or after your last treatment. Platelets help to make your blood clot when you hurt yourself. <strong>You may bruise or bleed more easily than usual.</strong></td>
<td>To help prevent bleeding problems:</td>
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<td>• Try not to bruise, cut, or burn yourself.</td>
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<td>• Clean your nose by blowing gently. Do not pick your nose.</td>
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<td>• Avoid constipation.</td>
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<td>• Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene.</td>
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<td>Some medications such as ASA (e.g. ASPIRIN®) or ibuprofen (e.g. ADVIL®) may increase your risk of bleeding.</td>
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<td>• Do not stop taking any medication that has been prescribed by your doctor (e.g. <strong>ASA for your heart</strong>).</td>
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<td>• For minor pain, try acetaminophen (e.g. TYLENOL®) first, but occasional use of ibuprofen may be acceptable.</td>
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<td><strong>Tiredness</strong> and lack of energy may occur.</td>
<td>Do not drive a car or operate machinery if you are feeling tired.</td>
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<td>Try the ideas in the handout titled <strong>Fatigue/Tiredness</strong></td>
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<td><strong>Hair loss is common</strong> with epirubicin, uncommon with fluorouracil and rare with oxaliplatin. Hair loss may begin within a few days or weeks of epirubicin treatment. Your hair may thin or you may become totally bald. Your scalp may feel tender. You may lose hair on your face and body. Your hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change.</td>
<td>• Use a gentle shampoo and soft brush.</td>
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<td>• Care should be taken with use of hair spray, bleaches, dyes and perms.</td>
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<td>• Protect your scalp with a hot, scarf or wig in cold weather. Some extended health plans will pay part of the cost of a wig.</td>
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<td>• Cover your head or apply sunblock on sunny days.</td>
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<td>• Apply mineral oil to your scalp to reduce itching.</td>
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<td>• If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-rimmed hat and glasses.</td>
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<td><strong>Your skin may redden</strong> where you have had radiation treatments.</td>
<td>This will slowly return to normal once you stop treatment with epirubicin.</td>
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<tr>
<td>OTHER SIDE EFFECTS DURING TREATMENT</td>
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| Your **skin may sunburn** easily.   | To help prevent sunburn:  
• 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. |
| **Skin rashes** may occur.          | To help itching:  
• You can use calamine lotion.  
• If very irritating, call your doctor during office hours.  
• Otherwise mention it at your next visit. |
| **Loss of appetite** is uncommon but may occur and may persist long after discontinuation of fluorouracil. | Try the ideas in *Food Ideas to Help with Decreased Appetite*. |
| **Abnormal heart rhythm** (QT prolongation) rarely occurs. | Minimize your risk of abnormal heart rhythm by:  
• Always checking with your pharmacist and doctor about drug interactions when starting a new medication, herbal product, or supplement.  
• Tell your doctor immediately or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded, or dizzy. |

* 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 epirubicin, doxorubicin, daunorubicin, idarubicin, mitoxantrone or mitomycin before starting epirubicin treatment, to oxaliplatin, cisplatin (PLATINOL®) or carboplatin (PARAPLATIN®) before starting oxaliplatin treatment, or to capecitabine or fluorouracil (5-FU, ADRUCIL®) before starting fluorouracil treatment.

• The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of epirubicin, oxaliplatin, or fluorouracil.

• Epirubicin and fluorouracil may cause sterility in men and menopause in women. If you plan to have children, discuss this with your doctor before being treated.

• Epirubicin, oxaliplatin and fluorouracil may damage sperm and 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, dentists and other health professionals that you are being treated with epirubicin, oxaliplatin, and fluorouracil before you receive any treatment from them.

Medication Interactions
Other drugs may interact with your chemotherapy treatment.

• Cimetidine (TAGAMET®) and verapamil (CHRONOVERA®, ISOPTIN®) may interact with epirubicin.

• Warfarin (COUMADIN®), phenytoin (DILANTIN®) and fosphenytoin (CEREBYX®) may interact with fluorouracil.

• 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 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 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 an allergic reaction (rare) soon after a treatment including dizziness, fast heart beat, face swelling or breathing problems.

• 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 bottoms of your feet.
• **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 skin reaction** where you have had radiation.
• **Severe skin irritation** or **skin rash** with or without itching.

**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.
• Redness, swelling, pain or sores where the needle was placed.
• Changes in fingernails or toenails.
• Heartburn; mild to moderate abdominal or stomach pain.
• Easy bruising or minor bleeding.
• Tingling or a loss of feeling in your hands, feet, nose or throat.
• Dizziness or trouble walking.
• 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: ________________