

For the Patient: GIFIRINOX

Other Names: Palliative Combination Chemotherapy for Metastatic Pancreatic Adneocarcinoma Using Irinotecan, Oxalipaltin, Fluorouracil and Folinic Acid (Leucovorin)

GI = GastroIntestinal

FIRINOX = Fluorouracil, Irinotecan, Infusional fluorouracil, Oxaliplatin

ABOUT THIS MEDICATION**What are these drugs used for?**

- Irinotecan, oxaliplatin, fluorouracil (5FU) and folinic acid (leucovorin) are drugs used to treat advanced cancer of the pancreas.

How do these drugs work?

- Irinotecan, oxaliplatin, and fluorouracil work by interfering with dividing cells and preventing an increase in the number of cancer cells.
- Leucovorin works by enhancing the effect of fluorouracil and strengthening fluoruracil's ability to reduce 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?**

- Irinotecan, oxaliplatin, fluorouracil, and leucovorin are all given directly into the vein (IV).
- You will receive irinotecan, oxaliplatin, fluorouracil, and leucovorin at the clinic by a chemotherapy nurse on the first day of treatment for **one day only**. You will then be given an additional dose of fluorouracil **over 46 hours**, or 2 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 46 hour time period. 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 2 days. You may return to the clinic after 2 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 12 day rest period.

- This two week 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 and a half 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 2 week cycle.

C Y C L E	DATE	TREATMENT PLAN
	1	
		Week 2 → no treatment

C Y C L E	DATE	TREATMENT PLAN
	2	
		Week 2 → no treatment

What will happen when I get my drugs?

- A **blood test** is done each cycle, on or before the first day of each 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 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.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Tell your nurse if you feel like you have difficulty breathing or swallowing during or immediately after your oxaliplatin infusion. This may occur rarely.</p>	<ul style="list-style-type: none"> • 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.
<p>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.</p>	<p>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.</p>
<p>Oxaliplatin and fluorouracil burn if either leaks under the skin.</p>	<p>Tell your nurse or doctor immediately 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 24- 48 hours.</p>	<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"> • Drink plenty of liquids. • Eat and drink often in small amounts. • Try the ideas in Practical Tips to Manage Nausea*
<p>Early diarrhea may occur, very commonly, during or shortly after an irinotecan treatment (within 24 hours). It starts with watery eyes, stomach cramps and sweating.</p>	<ul style="list-style-type: none"> • Tell your nurse or doctor immediately if you have watery eyes, stomach cramps or sweating during or after your treatment. • Early diarrhea is treated with a medication called atropine, which is injected into a vein or under your skin. If your cancer centre is closed, your cancer doctor may tell you to go to your Hospital emergency for atropine treatment.
<p>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.</p>	<ul style="list-style-type: none"> • 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	MANAGEMENT
<p>Late diarrhea may occur, very commonly, one day to several days after an irinotecan treatment. It starts with stools more loose or often than usual.</p>	<p>Late diarrhea must be treated immediately with loperamide 2 mg tablets (e.g. IMODIUM®):</p> <ul style="list-style-type: none"> • Take TWO tablets at the first sign of loose or more frequent stools than usual. • Then take ONE tablet every TWO hours until diarrhea has stopped for 12 hours. • At night, you may take TWO tablets every FOUR hours (set your alarm) during the time you usually sleep. • This dose is much higher than the package directions. It is very important that you take this higher dose to stop the diarrhea. • Always keep a supply of loperamide (e.g. have 48 tablets on hand). You can buy loperamide at any pharmacy without a prescription. <p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of liquids • Eat and drink often in small amounts • Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea* • A dietitian can give you more suggestions for dealing with diarrhea. <p>If diarrhea does not improve 24 hours after starting loperamide or lasts more than 36 hours, call your doctor.</p>
<p>Sore mouth may commonly 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 Food Ideas to Try with a Sore Mouth*

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Your white blood cells will decrease after your treatment, but usually return to normal within 2 weeks, before your next 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. • 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.

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 warm compresses or soak in warm water for 15-20 mins. several times a day.
<p>Fever may occur shortly after treatment with oxaliplatin. Fever should last no more than 24 hours.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g. TYLENOL®) every 3 – 4 hours. • Fever which occurs more than 48 hours after treatment may be the sign of an infection. See “white blood cells” above.
<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.
<p>Skin rashes are uncommon but may occur.</p>	<p>To help itching:</p> <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.

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.
Loss of appetite is uncommon but may occur and may persist long after discontinuation of fluorouracil.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
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 the handout titled Fatigue/Tiredness*
Hair loss is common with irinotecan and may begin within a few days or weeks of 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 changes.	<ul style="list-style-type: none"> • Use a gentle shampoo and soft brush. • Care should be taken with hair spray, bleaches, dyes and perms. • Protect your scalp with a hat, scarf or wig in cold weather. Some extended health plans will pay part of the cost of a wig. • Cover your head or apply sunblock on sunny days. • Apply mineral oil to your scalp to reduce itching. • If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-rimmed hat and glasses.
Abnormal heart rhythm (QT prolongation) rarely occurs.	Minimize your risk of abnormal heart rhythm by: <ul style="list-style-type: none"> • 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

- It is best to **avoid cold drinks** and exposure to **cold air**, especially on the day you receive oxaliplatin. On rare occasions, the cold temperature may make it difficult for you to swallow or breathe.
- You will be given a prescription for **anti-nausea drugs** to take prior to your chemotherapy. Bring your anti-nausea drugs with you, to take before your chemotherapy appointment. You will also need to take your anti-nausea drugs at home after therapy. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to the following drugs before starting this treatment:
 1. oxaliplatin, cisplatin (PLATINOL®) or carboplatin (PARAPLATIN®).
 2. fluorouracil or capecitabine (XELODA®).
 3. leucovorin
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of irinotecan, fluorouracil, or leucovorin.
- Fluorouracil may cause **sterility** in men and **menopause** in women. If you plan to have children, discuss this with your doctor before being treated with fluorouracil.
- Irinotecan, oxaliplatin and fluorouracil may damage sperm in males, and may harm the baby if used during pregnancy. It is best to **use birth control** while being treated with these drugs, and for six months after your last treatment. 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 irinotecan, oxaliplatin and fluorouracil before you receive any dental treatment

Medication Interactions

Some drugs may interact with leucovorin **and oxaliplatin**. Other drugs such as warfarin (COUMADIN®), phenytoin (DILANTIN®) and fosphenytoin (CEREBYX®) may **interact** with fluorouracil. Drugs such as laxatives, seizure medications (phenytoin, carbamazepine), St. John's Wort, dexamethasone or prochlorperazine may **interact with irinotecan**.

- Dexamethasone can be taken as an anti-nausea drug. Discuss with your cancer doctor if you are taking dexamethasone on a daily basis.
- Prochlorperazine should not be taken as an anti-nausea drug on the day of your irinotecan treatment.

Tell your doctor if you are taking this or any other drugs as you may need extra blood test 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.
- **Diarrhea** that occurs within the first 24 hours after irinotecan treatment.
- Signs of **severe fluid loss** due to diarrhea such as fainting, light-headedness or dizziness.
- 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.
- 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:

- **Severe diarrhea** that occurs after the first 24 hours and does not improve 24 hours after starting loperamide or lasts more than 36 hours.
- **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.
- 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.
- Tingling or a loss of feeling in your hands, feet, nose or throat.
- Redness, swelling, pain, or sores where the needle was placed.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Heartburn; mild to moderate abdominal or stomach pain.
- Dizziness or trouble walking.
- Trouble sleeping.
- Eye irritation or changes in eyesight.
- Skin rash or itching.

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: _____