

For the Patient: GIRAJFFOX

Other Names: Adjuvant combination chemotherapy for stage III rectal cancer using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)

GI = GastroIntestinal
R = Rectal
AJ = Adjuvant
FFOX = Fluorouracil, Folinic Acid, Oxaliplatin

ABOUT THIS MEDICATION

What are these drugs used for?

- Fluorouracil (5FU), folinic acid (leucovorin) and oxaliplatin are drugs given to treat cancer of the rectum.

How do these drugs work?

- Fluorouracil and oxaliplatin 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 fluorouracil's ability to reduce the number of cancer cells.

INTENDED BENEFITS

- You are being asked to take these drugs as a treatment to reduce the risk of recurrence of rectal cancer.
- “Adjuvant” therapy means this treatment is being given in addition to other types of treatment, such as surgery and radiation.

TREATMENT SUMMARY

How are these drugs given?

- Fluorouracil, leucovorin and oxaliplatin are given directly into the vein (IV).
- The oxaliplatin and leucovorin will be given first. These drugs are mixed separately into two IV bags, which are then given to you at the same time. You will then receive a dose of fluorouracil given directly into the vein through a syringe. 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 several days 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 two week rest period.

- This two week period of time is called a “cycle”. The cycles are repeated up to a maximum of 8 or 12 cycles, but may be changed depending on how the chemotherapy affects you.
- Each treatment will take **about 3 1/2 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 outlines your overall treatment plan.

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

Treatment is to be continued for a total of 8 or 12 cycles.

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 will burn if it 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. Some people have little or no nausea.</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. <p>Try the ideas in <i>Food Choices to Control Nausea*</i>.</p>
<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.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Diarrhea may occur during your treatment. This is very common.</p>	<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 & avoid high fibre foods as outlined in <i>Coping with Diarrhea*</i>.
<p>Sore mouth may occur during treatment. This is common. 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. <p>Try ideas in <i>Easy to Chew, Easy to Swallow Food Ideas*</i>.</p>
<p>Your white blood cells will decrease 7 – 10 days after your treatment. They usually return to normal 2 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.</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 <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.

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 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. This is common. 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.
<p>Your skin may sunburn easily.</p>	<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.
<p>Loss of appetite is uncommon but may occur and may persist long after discontinuation of fluorouracil.</p>	<p>Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i>.*</p>
<p>Tiredness and lack of energy may occur.</p>	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in Your Bank of Energy Savings: <i>How People with Cancer can Handle Fatigue</i>*

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Hair loss is uncommon with fluorouracil and rare with oxaliplatin. If you experience hair loss, your hair will grow back once you stop treatment. Colour and texture may change.</p>	<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.

***Please ask your chemotherapy nurse or pharmacist for a copy.**

INSTRUCTIONS FOR THE PATIENT

- 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 fluorouracil, oxaliplatin 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.
- Fluorouracil and oxaliplatin may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with fluorouracil. 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 oxaliplatin, fluorouracil or leucovorin before you receive any treatment from them.

Medication Interactions:

- Other drugs may **interact** with leucovorin. Other drugs such as warfarin (COUMADIN®), phenytoin (DILANTIN®) and fosphenytoin (CEREBYX®) may **interact** with fluorouracil and oxaliplatin. 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.
- 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**.
- **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.
- 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.
- 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: _____