For the Patient: GIAJFL
Other Names: Adjuvant therapy of colon cancer using Fluorouracil Injection and Infusion, and Folinic Acid (Leucovorin)

GI = GastroIntestinal
AJ = Adjuvant
FL = Fluorouracil, Leucovorin

ABOUT THIS MEDICATION

What are these drugs used for?
• Fluorouracil (also known as 5FU) and leucovorin are two drugs that are given to treat colon cancer. They are given directly into the vein (you may also hear the terms “intravenously” or IV”).

How do these drugs work?
• Fluorouracil works 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 the ability of fluorouracil 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 colon cancer.
• “Adjuvant” therapy means this treatment is being given in addition to other types of treatment, such as surgery.

TREATMENT SUMMARY

How are these drugs given?
• You will receive 5FU and leucovorin directly into the vein (IV). They will be given to you at the clinic by a chemotherapy nurse. The 5FU injection will take a few minutes for the nurse to give. The leucovorin infusion takes about 2 hours to be delivered to your body.
• You will then receive a 5FU infusion over 46 hours, using a disposable infusion device called an INFUSOR® or “baby bottle”. The infusion device delivers the 5FU slowly and continuously to your body over the 46 hour time period.
• 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 46 hours. You will either return to the clinic after the 46 hours 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.
• This treatment is repeated every 2 weeks. This 2 week or 14 day period of time is called a “cycle”. The cycle is usually repeated up to a maximum of 12 cycles, or about 6 months of time, but may be changed depending on how the chemotherapy affects you.

• Your treatment will probably take about 3 hours before you go home with the infusion device. 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 infusion device and chemotherapy drugs with you.

• Please see “Your Infusor® - A Guide for Patients”* for additional information.

The calendar below shows how the medications are given each 2 week cycle.

**Treatment Calendar**

<table>
<thead>
<tr>
<th>CYCLE</th>
<th>DATE</th>
<th>TREATMENT PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Week 1 ➔ Leucovorin IV on Day 1 + Fluorouracil IV on Day 1 + Fluorouracil Infusion over 46 hours starting on Day 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Week 2 ➔ no treatment</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CYCLE</th>
<th>DATE</th>
<th>TREATMENT PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Week 1 ➔ Leucovorin IV on Day 1 + Fluorouracil IV on Day 1 + Fluorouracil Infusion over 46 hours starting on Day 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Week 2 ➔ no treatment</td>
<td></td>
</tr>
</tbody>
</table>

Treatment is continued for a total of 12 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 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.

• You may be asked to suck ice chips as you receive treatment. This is to help reduce mouth sores that may develop following your treatment. If wearing dentures, you will be asked to remove them. Place the ice chips in your mouth five minutes before receiving the 5FU injection. Continuously swish the ice chips in your mouth for 30 minutes, adding more ice as it melts. This may cause some numbness or headaches, but these effects will disappear quickly.
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>
<thead>
<tr>
<th>SERIOUS SIDE EFFECTS DURING TREATMENT</th>
<th>MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Allergic reactions</strong> may 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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Fluorouracil</strong> burns if it leaks under the skin.</td>
<td>Tell your nurse of doctor immediately if you feel burning, stinging or any other change while the drug is being given.</td>
</tr>
</tbody>
</table>
| **Your white blood cells** will decrease 1-2 weeks after your last treatment. They usually return to normal 3 weeks after your treatment. This is a common side effect. 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 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine. |
| **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 outline in *Coping with 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. |
## SERIOUS SIDE EFFECTS DURING TREATMENT

**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 *Easy to Chew, Easy to Swallow Food Ideas*.

## OTHER SIDE EFFECTS DURING TREATMENT

**Pain or tenderness** may occur where the needle was placed.

Apply cool compresses or soak in cool water for 15-20 minutes several times a day.

**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.**

To help prevent bleeding problems:
- 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. Some medications such as ASA (e.g. ASPIRIN®) or ibuprofen (e.g. ADVIL®) may increase your risk of bleeding.
- 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.

**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.
### OTHER SIDE EFFECTS DURING TREATMENT

<table>
<thead>
<tr>
<th>Effect</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your skin may sunburn easily.</td>
<td>To help prevent sunburn:</td>
</tr>
<tr>
<td></td>
<td>• Avoid direct sunlight.</td>
</tr>
<tr>
<td></td>
<td>• Wear a hat, long sleeves and long pants or skirt outside on sunny days.</td>
</tr>
<tr>
<td></td>
<td>• Apply a sunscreen that blocks both UVA and UVB and has a sun protection factor (SPF) of at least 30. Apply liberally, 30 minutes before exposure. Reapply every 2 hours and after swimming.</td>
</tr>
<tr>
<td></td>
<td>• Consult the <em>BC Health Guide</em> or your community pharmacist for more information.</td>
</tr>
<tr>
<td>Loss of appetite may occur and may persist long after discontinuation of fluorouracil.</td>
<td>Try the ideas in <em>Food Ideas to Help with Decreased Appetite.</em></td>
</tr>
<tr>
<td>Hand-foot skin reaction is very rare but may occur during 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.</td>
<td>• Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity.</td>
</tr>
<tr>
<td>Hand-foot skin reaction is very rare but may occur during 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.</td>
<td>• Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water.</td>
</tr>
<tr>
<td>Hand-foot skin reaction is very rare but may occur during 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.</td>
<td>• Apply lanolin-containing creams (e.g. BAG BALM®, UDDERLY SMOOTH®) to hands and feet liberally and often.</td>
</tr>
<tr>
<td>Hand-foot skin reaction is very rare but may occur during 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.</td>
<td>• Try taking pyridoxine (vitamin B6) 50 – 150mg orally daily.</td>
</tr>
<tr>
<td>Hand-foot skin reaction is very rare but may occur during 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.</td>
<td>• Tell your cancer doctor at the next visit if you have any signs of hand-foot skin reaction.</td>
</tr>
<tr>
<td>Hair loss sometimes occurs with fluorouracil. Your hair will grow back once you stop treatment with fluorouracil. Colour and texture may change.</td>
<td>• Use a gentle shampoo and soft brush.</td>
</tr>
<tr>
<td>Hair loss sometimes occurs with fluorouracil. Your hair will grow back once you stop treatment with fluorouracil. Colour and texture may change.</td>
<td>• Care should be taken with use of hair spray, bleaches, dyes and perms.</td>
</tr>
<tr>
<td>Nausea does not usually occur with fluorouracil or leucovorin.</td>
<td></td>
</tr>
</tbody>
</table>

*Please ask your chemotherapy nurse or pharmacist 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 leucovorin, fluorouracil or to capecitabine (XELODA®) before using fluorouracil.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of 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.
- Fluorouracil 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 fluorouracil before you receive any treatment from them.

**Medication Interactions:**

- Other drugs may **interact** with leucovorin. Other drugs such as phenytoin (DILANTIN®) and warfarin (COUMADIN®) may **interact** with fluorouracil. 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.
- **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.
- 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: ___________________