



For the Patient: GIRINFRT

Adjuvant therapy for high risk cancer of the rectum using Capecitabine, Infusional Fluorouracil and Radiation therapy.

GI = GastroIntestinal

R = Rectal

INF = Infusional Fluorouracil

RT = Radiation Therapy

ABOUT THIS TREATMENT

What is this treatment used for?

- Fluorouracil (also known as 5FU) and capecitabine are drugs used to treat cancer of the rectum. Fluorouracil is a drug given directly into the vein, or intravenously (IV). Capecitabine is a tablet which is taken by mouth.
- Radiation therapy is a very effective therapy used to kill cancer cells by directing high-energy X-rays beams to a specific area of the body.

How do fluorouracil, capecitabine and radiation work?

- Fluorouracil and capecitabine work by interfering with dividing cells and preventing an increase in the number of cancer cells.
- Radiation also works by interfering with dividing cells by either killing them or stopping them from growing and reproducing.
- Fluorouracil also acts as a “radio-sensitizer”. That is, the fluorouracil makes the cancer cells more sensitive to the killing effect of the radiation. This is why the two types of treatment (radiation and chemotherapy) are used together at the same time.
- In this protocol, capecitabine is also used alone either before and/or after radiation treatment and surgery.

INTENDED BENEFITS

- You are being asked to take fluorouracil, capecitabine and radiation as a treatment to reduce the risk of recurrence of your rectal 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?

- The treatment is usually given using one of 3 different schedules. Your doctor(s) will choose Your treatment schedule based upon which option is best for the treatment of your cancer. Please see a description under “**Treatment Plan**” below for more information.

Fluorouracil

- For this protocol fluorouracil is **given only during radiation**. It is given directly into the vein (IV) using a disposable infusion device called an INFUSOR® or “baby bottle”. The infusion device delivers the fluorouracil slowly and continuously to your body over a 7 day time period. The infusion device will be given to you **weekly for five weeks**, for the duration of your radiation. 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. When you are not receiving radiation you can go home while your drug treatment is delivered over the 7 days. The chemotherapy nurse will disconnect the old infusion device and connect you with a new one, once a week, as you continue through your 5 weeks of fluorouracil and radiation therapy given together.
- Each connection will take about **1 hour**. 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.
- If your doctor decides to delay or stop your fluorouracil during radiation therapy due to side effects of the drug, your radiation will continue.

Capecitabine

- Capecitabine is a tablet taken by mouth. It is usually **given for 14 days, followed by a 7 day break**. This 21 day period of time is called a “**cycle**”. You will receive a total of six 21–day cycles, as long as you are not having too many side effects as determined by your doctor.
- Capecitabine may be given after completion of radiation and surgery. Sometimes it is given both before and after radiation and surgery (see description below under “Treatment Plan”, Option 1, 2 or 3).
- Capecitabine will be given to you by a pharmacist when you come in for each appointment with your doctor. You will be given enough tablets so you can take them while at home.

How is radiation given?

- Radiation therapy is offered at each of the five regional BC Cancer Agency Centres.
- Prior to starting treatment, you will attend the cancer centre to have your treatment planned. A CT scanner will take images which the radiation oncologist and radiation therapist will use to custom plan your treatment.
- Your treatment will start a few days after your planning appointment.
- A machine called a linear accelerator is used to generate and treat you with the high energy x-ray beams.
- Radiation treatments are given every day of the week except weekends and holidays.

Treatment Plan

Your doctor(s) have 3 options as to how you will be treated. The options are described below.

Option 1:

- Radiation therapy and fluorouracil at the same time for 5 weeks.
- Surgery follows completion of radiation and fluorouracil treatment.
- Treatment with 6 cycles of capecitabine alone, starting about 4 to 8 weeks after surgery, depending on how you recover from surgery.

DATE	CYCLE	TREATMENT PLAN
		▶ Radiation: 25 fractions given over 5 weeks (may take 5 – 6 weeks)
	1	▶ Infusional fluorouracil given weekly for five weeks, combined with radiation
		▶ Surgery
	2 - 7	▶ Capecitabine orally in a.m. & p.m. x 14 days then off for 7 days (Cycle 2 Starts about 4 to 8 weeks after surgery, depending on recover. One cycle is 21 days)

Option 2:

- Capecitabine alone given for 1 cycle.
- Radiation therapy and fluorouracil at the same time for 5 weeks.
- Surgery follows completion of radiation and fluorouracil treatment.
- Additional 5 cycles of capecitabine alone, starting about 4 to 8 weeks after surgery, depending on how you recover from surgery.

DATE	CYCLE	TREATMENT PLAN
	1	▶ Capecitabine orally in a.m. & p.m. x 14 days then off for 7 days
		▶ Radiation: 25 fractions given over 5 weeks (may take 5 – 6 weeks)
	2	▶ Infusional fluorouracil given weekly for five weeks, combined with radiation
		▶ Surgery
	3 - 7	▶ Capecitabine orally in a.m. & p.m. x 14 days then off for 7 days (Cycle 3 Starts about 4 to 8 weeks after surgery, depending on recover. One cycle is 21 days)

Option 3:

- Capecitabine alone given for 2 cycles.
- Radiation therapy and fluorouracil at the same time for 5 weeks.
- Surgery follows completion of radiation and fluorouracil treatment.
- Additional 4 cycles of capecitabine alone, starting 4 to 8 weeks after surgery, depending on how you recover from surgery.

DATE	CYCLE	TREATMENT PLAN
	1 & 2	▶ Capecitabine orally in a.m. & p.m. x 14 days then off for 7 days
		▶ Radiation: 25 fractions given over 5 weeks (may take 5 – 6 weeks)
	3	▶ Infusional fluorouracil given weekly for five weeks, combined with radiation
		▶ Surgery
	4 - 7	▶ Capecitabine orally in a.m. & p.m. x 14 days then off for 7 days (Cycle 3 starts about 4 to 8 weeks after surgery, depending on recover. One cycle is 21 days)

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.

What will happen when I get radiation?

- Radiation treatments are delivered every day of the week except weekends and holidays. You will continue to take your fluorouracil over the weekends.
- The length of your treatment appointment will be approximately 15 minutes, but you will be receiving radiation for only a few minutes.
- While the radiation is being given, the radiation therapists will not be in the room with you. They will be watching you on a video camera and you can talk with them over the microphone.
- You will not feel anything during the radiation treatments.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Chemotherapy

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 and how to manage those side effects with you on the day you receive your first treatment. The pharmacist will review how to take the capecitabine and possible side effects with you on the day you first pick up your medication.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Fluorouracil burns if it leaks under the skin.	Tell your nurse or doctor immediately if you feel burning, stinging or any other change while the drug is being given.
Hand-foot skin reaction may occur very commonly during capecitabine 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.	<ul style="list-style-type: none"> • Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity. • Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. • Apply lanolin-containing creams (e.g. BAG BALM®, UDDERLY SMOOTH®) to hands and feet liberally and often. • Tell your cancer doctor at the next visit if you have any signs of hand-foot skin reaction. • Stop taking capecitabine and call your cancer doctor if the skin reaction is painful, as your dose may need to be changed. Taking a lower dose does not affect the usefulness of capecitabine.
Nausea and vomiting may occur while you are taking capecitabine. Many people have little or no nausea.	<p>You may be given a prescription for an anti-nausea drug(s) to take 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>Food Choice to Control Nausea*</i>.
Diarrhea may occur.	<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 food as outlined in <i>Coping with Diarrhea*</i> • Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID® tablets just before your capecitabine dose. • Stop taking capecitabine and call your cancer doctor if you have four stools a day more than usual or diarrhea during the night, as your dose may need to be changed.

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>Easy to Chew, Easy to Swallow Food Ideas*</i>.
<p>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.</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.

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

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	Apply warm compresses or soak in warm 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. 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: <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. Some medications such as ASA (e.g. ASPIRIN®) or ibuprofen (e.g. ADVIL®) may increase your risk of bleeding. <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.
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 <i>Your Bank of Energy Savings: How People with Cancer can Handle Fatigue*</i>.
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 15.
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 make sure to mention it at your next visit.
Loss of appetite may occur and may persist long after discontinuation of fluorouracil	Try the ideas in <i>Food Ideas to Help with Decreased Appetite*</i> .
Hair loss sometimes occurs with fluorouracil. 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 use of hair spray, bleaches, dyes and perms.

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

Radiation

- Prior to starting treatment, your radiation oncologist and radiation therapist will provide you with information on the side effects you may experience. You will also be provided with information on how to manage these side effects.
- The most common side effects are fatigue, bowel urgency, loose bowel movements and possible bladder irritation. The radiation therapists will assess you daily.
- Once a week you will be scheduled to meet with your radiation oncologist which will mean you will be at the cancer centre a little longer.
- Nurses, dietitians and other health care professionals are available to help support you during treatment.

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever had an unusual or allergic reaction to fluorouracil or capecitabine (XELODA®) before taking these medications.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of fluorouracil or capecitabine.
- 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 capecitabine 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 or dentists that you are being treated with capecitabine before you receive any treatment from them.

Capecitabine

- Capecitabine is taken by mouth **twice a day**, about 12 hours apart, with equal numbers of tablets taken at each dose. You may be given tablets of more than one strength to make the right dose. Capecitabine should be taken within 30 minutes following the end of a meal (breakfast and dinner) with a glass of water.
- The tablet contains lactose.
- If you **vomit after taking capecitabine**, do not take a second dose. Call your doctor during office hours for advice.
- If you **miss a dose of capecitabine**, take it as soon as you can if it is within 6 hours of the missed dose. If it is over 6 hours since the missed dose, skip the missed dose and go back to the usual dosing time. Call your doctor during office hours to ask about making up the missed dose.
- Sometimes capecitabine treatment has to be **stopped for a short time** because of side effects. When you **restart** capecitabine treatment, do not make up for the missed dose; instead, take as directed by your cancer doctor and finish the treatment on the same day as originally planned. For example, if you stop on day 3 of your 14-day treatment course and then restart at a later day, you would still take the last dose on day 14. You may be told to take a different dose and you may have extra tablets left over. Return the extra tablets to the clinic at your next visit. Taking a lower dose does not affect the usefulness of capecitabine.
- **Store** capecitabine tablets out of the reach of children, at room temperature, away from heat, light and moisture.

Medication Interactions

Some drugs such as warfarin (COUMADIN®), phenytoin (DILANTIN®) and fosphenytoin (CEREBYX®) may **interact with capecitabine and fluroruracil**. 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

STOP TAKING CAPECITABINE, 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 lower legs, or fainting.
- Sudden **abdominal pain** or tenderness.
- **Uncontrolled nausea, vomiting, or diarrhea.**

STOP TAKING CAPECITABINE AND 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.
- **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 abdominal or stomach cramping or pain.**
- **Severe skin irritation**, including where you have had radiation.

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.
- Uncontrolled loss of appetite or constipation.
- Easy bruising or minor bleeding.

- Redness, swelling, pain, or sores where the needle was placed.
- Skin rash or itching.
- Changes in fingernails or toenails.
- Heartburn; mild to moderate abdominal or stomach pain.
- Dizziness or trouble walking.
- Eye irritation, watery eyes 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: _____