

For the Patient: GIFUART

Other Names: Curative-intent combined treatment for cancer of the anal canal using Mitomycin, Infusional Fluorouracil and Radiation Therapy

GI = GastroIntestinal
FU = Fluorouracil
A = Anal
RT = Radiation Therapy

ABOUT THIS MEDICATION

What is this treatment used for?

- Mitomycin and Fluorouracil are drugs used to treat cancer of the anal canal. They are given directly into the vein or intravenously (IV).
- 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 mitomycin, fluorouracil and radiation work?

- Mitomycin and fluorouracil 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.
- Mitomycin and fluorouracil also act as a “radio-sensitizer”. That is, the mitomycin and fluorouracil make 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.

INTENDED BENEFITS

- This therapy is being given to treat your cancer of the anal canal with the intention of cure.

TREATMENT SUMMARY

How are these drugs given?

- Mitomycin and fluorouracil are given directly into the vein (IV).
- You will receive **mitomycin** at the clinic by a chemotherapy nurse on the first day of treatment **i.e. on week 1, day 1 and optionally on week 5, day 1** of your treatment.
- You will receive **fluorouracil** at the clinic by the chemotherapy nurse on **day 1 and day 3** of your treatment. The fluorouracil is given using TWO disposable infusion devices called an INFUSOR® or “baby bottle”. Each infusion device delivers the fluorouracil slowly and continuously to your body **over 48 hours or 2 days**. Please see a copy of “*Your INFUSOR® - A Guide for Patients*”, available through your chemotherapy nurse.
- The infusion device may be connected to your veins directly, or 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 about your normal pattern of living, while your **FIRST** fluorouracil infusor device delivers treatment over the 48 hours or 2 days. You will return to clinic on day 3. The **SECOND** infusion device will be connected to your IV site by the chemotherapy nurse. You can go home while your fluorouracil treatment is delivered over the next 48 hours. Total time period of IV fluorouracil infusion is 96 hours or 4 days. You may return to the clinic after 4 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.
- The mitomycin and fluorouracil treatment will take **about 1 hour**. Your first treatment may take longer, as the nurse will review information on the chemotherapy drugs and infusion device with you. As well, you will need weekly dressing changes if you have a PICC line. These dressing changes are done by the chemotherapy nurse, and usually take about 10 – 15 minutes.

How is radiation therapy 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 give the high energy x-rays.
 - Radiation treatments are given every day of the week except weekends and holidays.

The calendar below shows how the medications are given.

	DATE	TREATMENT PLAN
C Y C L E 1		Radiation Therapy 28 fractions over 5 ½ weeks
		▶ Week 1 → Mitomycin IV x 1 day → FIRST Fluorouracil infusion x 48 hours, starting on day 1
		▶ Week 1 → SECOND Fluorouracil infusion x 48 hours, starting on day 3
		▶ Week 2 → Radiation therapy only
		▶ Week 3 → Radiation therapy only
		▶ Week 4 → Radiation therapy only
		▶ Week 5 → (Optional) Mitomycin IV x 1 day → FIRST Fluorouracil infusion x 48 hours, starting on day 1
		▶ Week 5 → SECOND Fluorouracil infusion x 48 hours, starting on day 3
		▶ Week 6 → Radiation therapy only

What will happen when I get my drugs?

- A **blood test** is done on or before the first day of treatment. 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 therapy?

- Radiation treatments are delivered every day of the week except weekends and holidays.
- 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 mitomycin and fluorouracil, and how to manage those side effects with you on the day you receive your first treatment.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Allergic reactions may occur but are very rare. 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>Mitomycin 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>With mitomycin, nausea and vomiting may occur after your treatment and may last for 48 – 72 hours. Generally speaking, most people have little or no nausea.</p> <p>While on the fluorouracil infusion, nausea does not usually occur.</p>	<p>You may be given a prescription for 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 fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Help Manage Nausea*</i> <p>Your doctor may manage delayed nausea and vomiting differently. Be sure to let your doctor know if you experience this.</p>

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Diarrhea may occur.</p>	<p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of liquids. • Eat and drink often in small amounts. • Eat low fibre foods & avoid high fibre foods as outlined in <i>Food Ideas to Help Manage Diarrhea</i>.* <p>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:</p> <ul style="list-style-type: none"> • 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
<p>Sore mouth may occur a few days after 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 ideas in <i>Food Ideas to Try with a Sore Mouth</i>*.
<p>Your white blood cells may decrease 7 – 14 days after your treatment. They usually return to normal 30 days 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. • Avoid crowds and people who are sick. • 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.
<p>Cough and/or shortness of breath may rarely occur</p>	<p>Bring this to the attention of your doctor immediately as these may be early signs of toxicity to your lungs.</p>

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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.
Fever may sometimes occur shortly after treatment with mitomycin. Fever should last no longer than 24 hours.	<ul style="list-style-type: none"> • Take acetaminophen (e.g. TYLENOL®) every 4 – 6 hours, to a maximum of 4 g (4000 mg) per day. • Fever which occurs more than a few days after treatment may be a sign of an infection. Report this to your doctor immediately.
Your skin may sunburn easily.	<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 sunscreen 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.
Your platelets may decrease 7 – 14 days after your treatment. They usually return to normal 30 days 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>To 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.
Skin rashes may occur.	<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 make sure to mention it at your next visit.
Nail changes such as change in colour or the appearance of bands may sometimes occur.	This will return to normal when you stop taking mitomycin.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Tiredness and lack of energy may sometimes 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>*
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 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.

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, proctitis, perineal skin toxicity 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, dieticians 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 receiving treatment.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of mitomycin or fluorouracil.
- 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 mitomycin 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. Tell

your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.

- **Tell** doctors, dentists and other health care professionals that you are being treated with fluorouracil and mitomycin before you receive any treatment from them.

Medication Interactions

Some drugs may interact with fluorouracil, such as warfarin (COUMADIN®), phenytoin (DILANTIN®) and fosphenytoin (CEREBYX®). Other drugs may interact with mitomycin. 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 **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); shaking chills; severe sore throat; cough; pain or burning when you pass urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **bleeding problems** such as black, tarry stools, blood in urine, pinpoint red spots on skin, extensive bruising.
- **Cough** and/or **shortness of breath**.
- 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.**

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 **kidney problems** such as lower back or side pain, swelling of feet/lower legs.
- Signs of **bladder problems** such as changes in urination, painful burning sensation, presence of blood, or abdominal pain.
- **Severe skin irritation.**
- **Excessive thirst** or **increased** quantity or frequency of urination.

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: _____