



For the Patient: GICART

Other Names: Curative therapy for cancer of the anal canal using combined Mitomycin, Capecitabine and Radiation Therapy

GI = GastroIntestinal

CA = Capecitabine, Mitomycin

RT = Radiation Therapy

ABOUT THIS TREATMENT

What is this treatment used for?

- Capecitabine and Mitomycin are drugs used to treat cancer of the anal canal.
- Capecitabine is a tablet that is taken by mouth, and mitomycin is 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 capecitabine, mitomycin and radiation therapy work?

- Capecitabine and mitomycin 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.
- Capecitabine and mitomycin also act as “radio-sensitizers”. That is, the drugs 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?

- You will receive mitomycin directly into the vein (IV). Capecitabine is a tablet taken by mouth.
- You will receive **mitomycin** at the clinic by a chemotherapy nurse on the first day of treatment for **one day only**. This treatment will take about 30 minutes.
- You will be given **capecitabine** tablets to start on the same day as the mitomycin. Capecitabine is usually taken **twice a day**, 10 to 12 hours apart, with equal numbers of tablets taken at each dose. You may be given tablets of more than one strength to make up the right dose. Capecitabine is best taken within 30 minutes following the end of a meal (usually breakfast and dinner) with a glass of water. With this protocol, capecitabine is taken for **five days in a row**, Monday to Friday, in combination with radiation therapy. Capecitabine is **not taken** on Saturday or Sunday. You will take capecitabine for the duration of radiation therapy, which is six weeks.
- Only **one week supply** of capecitabine is given to you at a time. Blood work must be checked as you go through treatment, and will be reviewed each week before the capecitabine is given to you. You must **visit the pharmacy** to pick up your capecitabine tablets each week.

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, no gap
		▶ Week 1 → mitomycin IV x 1 day → capecitabine orally twice a day with food x 5 days (Monday to Friday. Second dose should be taken 10 to 12 hours after first dose).
		▶ Week 2 → capecitabine orally twice a day with food x 5 days (Monday to Friday. Second dose should be taken 10 to 12 hours after first dose).
		▶ Week 3 → capecitabine orally twice a day with food x 5 days (Monday to Friday. Second dose should be taken 10 to 12 hours after first dose).
		▶ Week 4 → capecitabine orally twice a day with food x 5 days (Monday to Friday. Second dose should be taken 10 to 12 hours after first dose).
		▶ Week 5 → capecitabine orally twice a day with food x 5 days (Monday to Friday. Second dose should be taken 10 to 12 hours after first dose).
		▶ Week 6 → capecitabine orally twice a day with food x 5 days (Monday to Friday. Second dose should be taken 10 to 12 hours after first dose).

What will happen when I get my drugs?

- A **blood test** is done on or before the first day of treatment. Weekly blood tests will be done during capecitabine 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 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
Mitomycin 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.
Diarrhea may occur during your treatment with capecitabine.	To help diarrhea: <ul style="list-style-type: none">• Drink plenty of liquids• Eat and drink often in small amounts.• Avoid high fibre foods as outlined in <i>Food ideas to help with diarrhea during chemotherapy*</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 usually or diarrhea during the nights, as your dose may need to be changes.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Your white blood cells will decrease during or after your treatment. They usually return to normal 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.	To help prevent infection: <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Take care of your skin and mouth. • 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.
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.	<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>.
Cough and/or shortness of breath may rarely occur.	Bring this to the attention of your doctor immediately as these may be early signs of toxicity to your lungs.

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.
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.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Nausea and vomiting may occur after your treatment and may last for 48 - 72 hours. Most people have little or no nausea.</p>	<p>You will 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 liquids. • Eat and drink often in small amounts. • Try the ideas in <i>Food Choice to Control Nausea*</i>
<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>Nail changes such as change in colour or the appearance of bands may sometimes occur.</p>	<p>This will return to normal when you stop taking mitomycin.</p>
<p>Tiredness and lack of energy may sometimes 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 <i>Your Bank of Energy Savings: How People with Cancer can Handle Fatigue*</i>.
<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 may sometimes occur.</p>	<p>Try the ideas in <i>Food Ideas to Help with Decreased Appetite*</i>.</p>
<p>Hair loss is rare. 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.

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, 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 (5 FU, ADRUCIL®) before taking capecitabine.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of mitomycin or capecitabine.
- Mitomycin 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 mitomycin and capecitabine before you receive any dental treatment.

Capecitabine

- 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**. 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 **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.
- Signs of **heart problems** such as fast or uneven heartbeat, shortness of breath or difficulty breathing and pain or pressure in the chest, jaw or arm.
- **Cough** and/or **shortness of breath**.
- **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 bottoms of your feet. If there is a delay in seeing your doctor, stop taking your capecitabine tablets until you are seen or have discussed with your doctor.
- **Diarrhea** with four stools a day more than usual, or diarrhea during the night.
- Signs of **anemia** such as unusual tiredness or weakness.
- **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 kidney problems such as lower back or side pain, swelling of feet or lower legs.
- Signs of bladder problems such as changes in urination, painful burning sensation, presence of blood, or abdominal pain.
- **Severe abdominal or stomach cramping or pain**.
- Signs of **heart problems** such as swelling of feet or lower legs
- **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,
- Painless redness, swelling or sores on your lips, tongue, mouth or throat.
- 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.
- Severe skin reaction where you have had radiation.
- Watery, irritated eyes.

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: _____