

For the Patient: GIRAJCOX

Other Names: Adjuvant combination chemotherapy for Stage III rectal cancer using capecitabine and oxaliplatin.

GI = GastroIntestinal

R = Rectal AJ = Adjuvant

COX = Capecitabine, Oxaliplatin

ABOUT THIS MEDICATION

What are these drugs used for?

• Capecitabine and oxaliplatin are drugs given to treat cancer of the rectum.

How do these drugs work?

 Both capecitabine and oxaliplatin work by interfering with dividing cells and preventing an increase in 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 your rectal cancer.
- "Adjuvant" therapy means this treatment is being given in addition to other types of treatment, such as surgery or radiation.

TREATMENT SUMMARY

How are these drugs given?

- Oxaliplatin is given directly into the vein (IV) and capecitabine is a tablet taken by mouth.
- You will receive the oxaliplatin at the clinic by a chemotherapy nurse on the first day of treatment for one day only. You will be given the capecitabine to start on the same day. Capecitabine is usually given for 14 days, followed by a 7 day break. You will take this medication home with you. This 21 day period of time is called a "cycle". The cycles are repeated up to a maximum of 6 or 8 cycles, but may be changed depending on how the chemotherapy affects you.
- Each oxaliplatin treatment will take **about 2 and a half hours**. Your first treatment will probably take longer, as the nurse will review information on the chemotherapy drug with you.
- Capecitabine will be given to you by a pharmacist when you come in for each oxaliplatin treatment. You will be given enough tablets so you can take them while at home.

The calendar on the following page shows how the medications are given each 3 week cycle.

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C Y	DATE	TREATMENT PLAN	
C L E		 Week 1 → oxaliplatin IV x 1 day → capecitabine orally in a.m.& p.m. x 7 days with food. 	
1		Week 2 → capecitabine orally in a.m.& p.m. x 7 days with food.	
		Week 3 → No Treatment	

Treatment can be given pre-surgery or post surgery. It is continued for a total of 6 to 8 cycles, as long as you are benefitting 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 treatment 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 oxaliplatin 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	MANAGEMENT
DURING TREATMENT	
Tell your nurse if you feel like you have difficulty breathing or swallowing during or immediately after your oxaliplatin infusion. This may occur rarely.	 These symptoms will disappear in a few hours, and my not require treatment. If you have these symptoms with a 2-hour infusion, your next treatment may be given over 6 hours.
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.	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.
Oxaliplatin 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 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.	 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 (eg. 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 after your oxaliplatin treatment and may last for 24- 48 hours. Nausea and vomiting may also occur while you are taking capecitabine.	You may be given a prescription for an antinausea 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. • Drink plenty of liquids. • Eat and drink often in small amounts. Try the ideas in <i>Practical Tips to Help Manage Nausea</i> .*

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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. These problems often disappear after a few hours or days.	 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. Try the ideas in Coping With/Preventing Oxaliplatin Cold Dysesthesias*.
Diarrhea may occur during your treatment.	 Drink plenty of fluids Eat and drink often in small amounts Eat low fibre foods & avoid high fibre foods as outlined in Food Ideas to Help Manage 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 Stop taking capecitabine and call your cancer doctor if you have four stools a day more than usual or diarrhea during the night, or a moderate increase in ostomy output, as your capecitabine dose may need to be changed. 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.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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 Food Ideas to Try with a Sore Mouth*.
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.	 To help prevent infection: 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
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 occur shortly after treatment with oxaliplatin. Fever should last no longer than 24 hours.	 Take acetaminophen (e.g. TYLENOL®) every 3-4 hours. Fever which occurs more than 48 hours after treatment maybe the sign of an infection. See details under Serious Side Effects above
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: 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.
Tiredness, fatigue and lack of energy may occur. As the number of treatment cycles increase, fatigue may get worse.	 Do not drive a car or operate machinery if you are feeling tired. Try the ideas in the handout titled Fatigue/Tiredness*.
Your skin may sunburn easily from the capecitabine.	 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 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.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Hair loss is rare with oxaliplatin and capecitabine. Your hair will grow back once you stop treatment. Colour and texture may change.	 Use a gentle shampoo and soft brush. Care should be taken with use of hair spray, bleaches, dyes and perms. If hair loss is a problem, refer to Resources for Hair Loss and Appearance Changes*.
Abnormal heart rhythm (QT prolongation) rarely occurs.	Minimize your risk of abnormal heart rhythm by:
	 Always checking with your pharmacist and doctor about drug interactions when starting a new medication, herbal product, or supplement.
	Tell your doctor immediately or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded, or dizzy.

^{*}Please ask your chemotherapy nurse, pharmacist or dietitian for a copy.

Special note:

Heart Problems: Serious heart problems can occur when starting capecitabine. 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 fluorouracil, 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 capecitabine. If your symptoms are severe, you may need to call for emergency help.

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever hand an unusual or **allergic reaction** to cisplatin (PLATINOL®) or carboplatin (PARAPLATIN®) before starting oxaliplatin treatment, or to fluorouracil (5FU, ADRUCIL®) before taking capecitabine.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of oxaliplatin or capecitabine.
- Oxaliplatin 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, dentists and other health professionals that you are being treated with oxaliplatin and capecitabine before you receive any treatment from them.

BC Cancer Protocol Summary (Patient Version) GIRAJCOX Developed: 01 Nov 2012

Capecitabine

- Capecitabine is taken by mouth twice a day, about 10-12 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. It is usually given for 14 days, followed by a 7
 day break.
- 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. Let your doctor know during office hours if you have missed a 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. 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 YOUR CAPECITABINE AND SEE YOUR DOCTOR <u>OR</u> 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 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.
- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heart beat, face swelling, or breathing problems.
- Seizures or loss of consciousness with or without confusion, headache, or changes in eyesight.

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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.
- 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.

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 nausea, vomiting, loss of appetite, diarrhea or constipation.
- Skin rash or itching.
- · Changes in fingernails or toenails.
- Heartburn; mild to moderate abdominal or stomach pain.
- 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.
- 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:

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