

For the Patient: GIAVRALIR

Other Names: Palliative Treatment of Metastatic Colorectal Cancer Using Irinotecan and Raltitrexed in Patients Intolerant to Fluorouracil or Capecitabine

GI = GastroIntestinal AV = Advanced

RALIR = **Ral**titrexed, **Ir**inotecan

ABOUT THIS MEDICATION

What are these drugs used for?

• Irinotecan and raltitrexed are drugs given to treat cancer of the colon or rectum.

How do these drugs work?

• Both irinotecan and raltitrexed work by interfering with dividing cells and preventing an increase in the number of cancer cells.

INTENDED BENEFITS

- This therapy is being given to destroy and/or limit the growth of cancer cells in your body.
- This treatment may improve your current symptoms and delay the onset of new symptoms.

TREATMENT SUMMARY

How are these drugs given?

- Irinotecan and raltitrexed are given directly into the vein (IV). They will be given to you at the clinic by a chemotherapy nurse. Each treatment will take about **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.
- The treatment is repeated every 3 weeks. This 3 week or 21-day period of time is called a "cycle".

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

C Y C	DATE	TREATMENT PLAN		
E		► Week 1 → irinotecan and raltitrexed IV x 1 day		
		Week 2 🗲 No Treatment		
		Week 3		

Treatment is continued as long as you are benefiting from treatment and not having too many side effects, as determined by your oncologist.

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 raltitrexed and how to manage those side effects with you on the day you receive your first treatment.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
A flu-like illness may occur shortly after treatment with raltitrexed. You may have fever, chills, headache, muscle aches and joint aches. Flu-like symptoms usually disappear on their own. Fever should last no longer than 24 hours.	 Take acetaminophen (e.g. TYLENOL®) every 3-4 hours. Fever (over 100°F or 38°C by an oral thermometer) which occurs more than 48 hours after treatment maybe the sign of an infection. Report to your doctor <u>immediately.</u> You will be given a prescription for an
irinotecan treatment and may last for 24 hours. Nausea and vomiting may also occur 2-3 days after your raltitrexed treatment.	 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 the <i>Practical Tips to Help Manage Nausea</i>*
Early diarrhea may occur during or shortly after an irinotecan treatment (within 24 hours). It starts with watery eyes, stomach cramps and sweating.	 Tell your nurse or doctor <i>immediately</i> if you have watery eyes, stomach cramps or sweating during or after your treatment. Early diarrhea is treated with a medication called atropine, which is injected into a vein or under your skin. If your cancer centre is closed, your cancer doctor may tell you to go to your Hospital Emergency for atropine treatment.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Late diarrhea may occur one day to several days after an irinotecan treatment. It starts with stools more lo	 Late diarrhea must be treated <u>immediately</u> with loperamide 2 mg tablets (eg, Imodium®): Take <u>TWO tablets</u> at the first sign of loose or more frequent stools than usual. Then take <u>ONE tablet</u> every <u>TWO hours</u> until diarrhea has stopped for 12 hours. At night, you may take <u>TWO tablets</u> every <u>FOUR hours</u> (set your alarm) during the time you usually sleep. This dose is much higher than the package directions. It is very important that you take this higher dose to stop the diarrhea. Always keep a supply of loperamide (eg, have 48 tablets on hand). You can buy loperamide at any pharmacy without a prescription. To help diarrhea: Drink plenty of liquids. Eat and drink often in small amounts. Avoid high fiber foods as outlined in Food Ideas to Help Manage Diarrhea* A dietitian can give you more suggestions for dealing with diarrhea If diarrhea does not improve 24 hours after starting loperamide or lasts more than 36 hours, call your doctor.
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. Avoid crowds and people who are sick. Call your doctor doctor <i>immediately</i> 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
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 <i>Food Ideas to Try with a Sore Mouth*.</i>
Swelling of hands, feet or lower legs may occur if your body retains extra fluid.	If swelling is a problem:Elevate your feet when sitting.Avoid tight clothing.
Headaches may occur. These are usually mild.	Take acetaminophen (eg, Tylenol®) every 4-6 hours if need, to a maximum of 4 g (4000 mg) per day.
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 <i>Fatigue/Tiredness*.</i>
Pain or tenderness may occur where the needle was placed You may have trouble sleeping.	 Apply cool compresses or soak in cool water for 15-20 minutes several times a day. Talk to your doctor if your trouble in sleeping continues to bother you. This will return to normal when you stop treatment with irinotecan.
Hair loss is common with irinotecan and may begin within a few days or weeks of treatment. Hair loss is rare with raltitrexed. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. In most cases, your hair will grow back once your treatments are over and sometimes between treatments. 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. Protect your scalp with a hat, scarf or wig in cold weather. Some extended health plans will pay part of the cost of a wig. Cover your head or apply sunblock on sunny days. Apply mineral oil to your scalp to reduce itching. If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-rimmed hat and glasses If hair loss is a problem, refer to <i>Resources for Hair Loss and Appearance Changes*.</i>

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

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever hand an unusual or **allergic reaction** to irinotecan (before starting treatment.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of irinotecan or raltitrexed.
- Irinotecan and raltitrexed 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, and for 6 months following the last raltitrexed treatment. 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 irinotecan and raltitrexed before you receive any dental treatment.

Medication Interactions

• Other drugs such as folic acid, leucovorin (folinic acid) or vitamin preparations containing folic acid or leucovorin may interact with raltitrexed. Do not take these products the day before or on the day of your raltitrexed treatment. 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 <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** such as fast or uneven heartbeat.
- **Diarrhea** that occurs within the first 24 hours after irinotecan treatment.
- Signs of **severe fluid loss** due to diarrhea such as fainting, light-headedness or dizziness.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Severe **diarrhea** that occurs after the first 24 hours <u>and</u> does not improve 24 hours after starting loperamide <u>or</u> lasts more than 36 hours.
- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **lung problems** such as shortness of breath or difficulty breathing.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Signs of **heart problems** such as shortness of breath or difficulty breathing, swelling of feet or lower legs.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Uncontrolled nausea, vomiting or diarrhea
- Easy bruising or minor bleeding.
- Redness, swelling, pain or sores where the needle was placed.
- Redness, swelling or sores on your lips, tongue, mouth or throat.
- Skin rash, itching, or peeling.
- Trouble sleeping.

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:_____at