

For the Patient: GIAVCETIR

Other Names: Third line treatment of metastatic cancer of the colon or rectum, using Cetuximab and Irinotecan

- **GI** = **G**astro**I**ntestinal
- AV = Advanced
- CET = Cetuximab
- IR = Irinotecan

ABOUT THIS MEDICATION

What are these drugs used for?

• Cetuximab and irinotecan are drugs given to treat cancer of the colon or rectum.

How do these drugs work?

• Irinotecan works by interfering with dividing cells and preventing an increase in the number of cancer cells. Cetuximab is a monoclonal antibody, a type of protein that also interferes with the growth 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.
- It may take several treatments before your doctor can judge whether or not this treatment is helping.

TREATMENT SUMMARY

How are these drugs given?

- Cetuximab and irinotecan are given directly into the vein (IV).
- You will receive cetuximab and irinotecan at the clinic by the chemotherapy nurse, for **one day only**. The cetuximab is given first, followed by the irinotecan. Your first treatment will last **about five hours**. Treatments after your first one will last **about four hours**. The first treatment is longer because the cetuximab is given more slowly and over a longer period of time, to make sure your body will accept the drug without any reaction. Usually, after the first treatment, the cetuximab can be given faster and over a shorter period of time.
- The treatment is repeated every 2 weeks. This 2 week period of time is called a "cycle". The cycle is usually repeated as long as you are benefiting from treatment and not having too many side effects, as determined by your oncologist.

The calendar below shows how the medications are given each 2 week cycle.

C DATE TREATMENT PLAN		TREATMENT PLAN
C L E		 Week 1 → Cetuximab IV over 2 hours on day 1, followed by 1 hour observation + Irinotecan IV over 90 minutes on day 1 Week 2 → No treatment
1		

C Y C	DATE	TREATMENT PLAN		
L E		► Week 1 → Cetuximab IV over 1 hour on day 1, followed by 1 hour observation + Irinotecan IV over 90 minutes on day 1		
2		► Week 2 → No treatment		

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

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Chills, fever and swelling commonly occur during the first cetuximab infusions. You may also experience shivering, problems breathing, dizziness, headache, or hoarseness. Reactions are less common with later treatments.	 Tell your nurse or doctor <i>immediately</i> if you have a reaction during your treatment. Your cetuximab may be temporarily stopped and then given more slowly. You may be given other drugs to treat the reaction.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Nausea and vomiting may occur after your treatment.	 You may be given a prescription for antinausea drugs(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 fluids Eat and drink often in small amounts Try the ideas in <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.
Late diarrhea may occur very commonly one day to several days after an irinotecan treatment. It starts with stools more loose or often than usual.	 Late diarrhea must be treated immediately with loperamide 2 mg tablets (e.g. IMODIUM®): Take <u>TWO tablets</u> at the first sign of loose or more frequent stools than usual. Then take <u>ONE tablet every TWO hours</u> until diarrhea has stopped for 12 hours. At night, you may take <u>TWO tablets every</u> <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 (e.g. 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 fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea*</i>. A dietician can give you more suggestions for dealing with diarrhea.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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.
Skin reactions such as acne, rash, dryness or itchiness commonly occur.	 Avoid direct sunlight and tanning salons during treatment and for 2 months following treatment. Wear a hat, long sleeves, and long pants outside on sunny days. Wear a sunscreen that blocks both UVA and UVB and has a sun protection factor (SPF) of at least 30. Apply liberally, 30 minutes before exposure. Reapply every 2 hours and after swimming. Frequent moisturizing with alcohol-free emollient creams is recommended. Do not use over-the counter acne preparations. Your doctor may prescribe a topical cream or oral antibiotic to manage the acne-like rash. Refer to <i>Your Medication Sun Sensitivity and Sunscreens*</i> or the <i>BC Health Guide</i> for more information If skin reaction persists or get worse, call your doctor. Otherwise, be sure to mention it at your next visit.
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>.

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.
Increased bone pain may sometimes occur.	You may take acetaminophen (e.g. TYLENOL®) every 4 – 6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g. ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity.
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.
Nail changes, especially of the big toes and thumbs, may occur.	If nails are painful, you may take acetaminophen (e.g. TYLENOL®) every 4 – 6 hours to a maximum of 4 g (4000 mg) per day o r ibuprofen (e.g. ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity. Otherwise, be sure to mention it at your next visit.
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 (e.g. TYLENOL®) every 4 – 6 hours if needed, to a maximum of 4 g (4000 mg) per day.
You may have trouble sleeping.	 Talk to your doctor if your trouble in sleeping continues to bother you. This will return to normal when you stop treatment with cetuximab and irinotecan.
Loss of appetite and weight loss are common.	Try the ideas in Food Ideas to Help with Decreased Appetite.*
Tiredness and lack of energy may occur.	 Do not drive a car or operate machinery if you are feeling tired. <i>Try the ideas in the handout titled Fatigue/Tiredness*</i>

Hair loss is common with irinotecan and may begin with a few days or weeks of treatment. Your hair may thin or you may become totally bald. Your scalp may feel tender. You may lose hair on your face and body. 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 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 had an unusual or **allergic reaction** to irinotecan or cetuximab or another monoclonal antibody before starting this treatment.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of cetuximab or irinotecan.
- Cetuximab and irinotecan may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with cetuximab. 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 cetuximab and irinotecan before you receive any treatment from them.

Medication Interactions

Other drugs such as laxatives, seizure medicines, St. John's Wort, dexamethasone or prochlorperazine may **interact** with irinotecan.

- Dexamethasone can be taken as an antinausea drug. Discuss with your cancer doctor if you are taking dexamethasone on a daily basis.
- Prochlorperazine should not be taken as an antinausea drug on the day of your irinotecan treatment.

Tell your doctor if you are taking any other drugs as 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.
- **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.
- 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.
- Seizures or loss of consciousness with or without confusion, headache, or changes in eyesight.
- Uncontrolled nausea, vomiting, or diarrhea.

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.
- Severe **skin reaction**, including the area around the nails that is painful, red, or swollen.
- Unusual tiredness or weakness.
- 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.
- Numbness or tingling in feet or hands.
- Changes in eyesight, eye pain, sensitivity to light, or severe eye redness.

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

- Dry mouth or increase thirst.
- Easy bruising or bleeding.
- Headache or other pain not controlled with acetaminophen (e.g. TYLENOL®)
- Redness, swelling, pain or sores where the needle was placed.
- Redness, swelling, pain or sores on your lips, tongues, mouth or throat.
- Skin rash or dry, itchy skin.
- Changes to eyelashes or eyebrow hair

• Confusion, anxiety or depression, or 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 telephone number:_____