

For the Patient: GIBAJCAP

Other Names: Adjuvant therapy of colon cancer using Capecitabine

GI = GastroIntestinal
B = Biliary
AJ = Adjuvant
CAP = Capecitabine

ABOUT THIS MEDICATION

What is this drug used for?

- Capecitabine is a drug given as therapy to treat biliary cancer. It is a tablet which is taken by mouth.

How does this drug work?

- Capecitabine works by interfering with dividing cells and preventing an increase in the number of cancer cells.

INTENDED BENEFITS

- You are being asked to take capecitabine as a treatment to reduce the risk of recurrence of biliary cancer after surgery.
- “Adjuvant” therapy means this treatment is being given in addition to other types of treatment, such as surgery or radiation.

TREATMENT SUMMARY

How is capecitabine given?

- 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.
- Capecitabine is usually **given for 14 days, followed by a 7 day break**. This 21 day period of time is called a “cycle”. The cycle is usually repeated up to a maximum of 8 treatments, but may be changed depending on how the chemotherapy affects you.
- 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.

The calendar below outlines how the medications are given every 3 week cycle.

| C Y C L E | DATE | TREATMENT PLAN |
|-----------------------|------|--|
| | 1 | |
| | | ▶ Week 2 → Capecitabine orally in a.m. & p.m. x 7 days with food |
| | | Week 3 → No Treatment |

What will happen when I get my drugs?

- A blood test is done each cycle, on or before the day of each treatment. 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 drug in your treatment plan.

Your doctor will review the risks of treatment and possible side effect with you before starting treatment. The pharmacist will review how to take the capecitabine and possible side effects with you the day you first pick up your medication.

| SERIOUS SIDE EFFECTS DURING TREATMENT | MANAGEMENT |
|--|--|
| <p>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.</p> | <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 (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. |
| <p>Diarrhea may occur during your treatment.</p> | <p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of fluids • 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>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.</p> <p>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.</p> |

| SERIOUS SIDE EFFECTS DURING TREATMENT | MANAGEMENT |
|--|---|
| <p>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.</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 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>. |
| <p>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.</p> | <p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Take care of your skin and mouth. • 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. |

| OTHER SIDE EFFECTS DURING TREATMENT | MANAGEMENT |
|--|--|
| <p>Nausea and vomiting may occur while you are taking capecitabine. Many people have little or no nausea.</p> | <p>You may be given a prescription for an 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>Practical Tips to Help Manage Nausea.*</i> |

| OTHER SIDE EFFECTS DURING TREATMENT | MANAGEMENT |
|---|---|
| <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>Tiredness and lack of energy may occur. worse.</p> | <ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in the handout titled <i>Fatigue/Tiredness*</i>. |
| <p>Your skin may sunburn easily from the capecitabine.</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 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. |
| <p>Hair loss is rare with capecitabine. 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. • 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.

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 had an unusual or **allergic reaction** to fluorouracil (5FU, ADRUCIL®) before taking capecitabine.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of capecitabine.
- 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 capecitabine before you receive any treatment from them.

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 CAPECITABINE AND 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, 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.

STOP TAKING CAPECITABINE AND 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.
- **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: _____