



For the Patient: GIGAVECC

Palliative therapy for metastatic or locally advanced stomach or esophageal cancer using Epirubicin, Cisplatin and Capecitabine

GIG = GastroIntestinal, Gastric

AV = Advanced

ECC = Epirubicin, Cisplatin, Capecitabine

ABOUT THIS MEDICATION

What are these drugs used for?

- Epirubicin, cisplatin and capecitabine are drugs given to treat metastatic or locally advanced cancer of the stomach or esophagus.

How do these drugs work?

- Epirubicin, cisplatin and capecitabine 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.
- It may take several treatments before your doctor can judge whether or not this treatment is helping.

TREATMENT SUMMARY

- Epirubicin and cisplatin are given directly into the vein (IV). Capecitabine is a tablet you take by mouth.
- You will receive epirubicin and cisplatin 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 21 days** or three weeks. You will take this medication home with you. This 21 day 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.
- Each treatment will take **about one 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 epirubicin and cisplatin 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.

C Y C L E	DATE	TREATMENT PLAN
		▶ Week 1 → Epirubicin IV + Cisplatin 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 → capecitabine orally in a.m. & p.m. x 7 days with food

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		▶ Week 1 → Epirubicin IV + Cisplatin IV x 1 day → capecitabine orally in a.m. & p.m. x 7 days with food.
	2	Week 2 → capecitabine orally in a.m. & p.m. x 7 days with food.
		Week 3 → capecitabine orally in a.m. & p.m. x 7 days with food

The cycles are continued as long as you are benefiting 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.
- Your doctor may ask you to **drink water** on the morning of your treatment (2 – 3 cups). Following your treatment your doctor may ask you to drink plenty of liquids (8 – 12 cups a day). This helps prevent kidney problems.

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 cisplatin and epirubicin, and how to manage those side effects with you on the day you receive your first treatment. The pharmacist will review possible side effects of capecitabine and how to manage those side effects with you on the day you receive your first treatment.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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.
Epirubicin and cisplatin both burn if the drug 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.	<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.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Nausea and vomiting may occur after your treatment and may last for up to 24 hours. Nausea may last longer for some patients (i.e. delayed nausea and vomiting).</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 doctor may manage delayed nausea and vomiting differently. Be sure to let your doctor know if you experience this.</p>
<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 and 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 night, as your dose may need to be changed.
<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.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>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.</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>Easy to Chew, Easy to Swallow Food Ideas*</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.
Your urine may be pink or reddish for 1-2 days after your treatment.	This is expected as epirubicin is read and is passed in your urine.
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>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.
Tiredness and lack of energy may occur.	<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>
Hair loss is common with epirubicin and may begin within 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.	<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. • 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.
Your skin may redden where you have had radiation treatments.	This will slowly return to normal once you stop treatment with epirubicin.
Your skin may sunburn easily.	<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.

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever had an **allergic reaction** to epirubicin, doxorubicin, daunorubicin, idarubicin, mitoxantrone, mitomycin, cisplatin or fluorouracil (5-FU, ADRUCIL®) before taking epirubicin, cisplatin or capecitabine.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of epirubicin, cisplatin, or capecitabine.
- Epirubicin and cisplatin may cause **sterility** in men and **menopause** in women. If you plan to have children, discuss this with your doctor before being treated.
- Epirubicin, cisplatin 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.
- Your doctor may ask you to take a **hearing test** before and at various times during your treatment with cisplatin. This helps to detect hearing problems.
- **Tell** doctors or dentists that you are being treated with epirubicin, cisplatin, and capecitabine before you receive any dental treatment.

Capecitabine

- Capecitabine is **taken by mouth** twice a day, about 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.
- 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

Other drugs may **interact** with your chemotherapy treatment.

- Cimetidine (TAGAMET®) and verapamil (CHRONOVERA®, ISOPTIN®) **may interact with epirubicin**.

- Some antibiotics given by vein (e.g. tobramycin, vancomycin), furosemide (LASIX®) and phenytoin (DILANTIN®) **may interact with cisplatin.**
- 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

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, pain or pressure in the chest, jaw or arm, shortness of breath, difficulty breathing or fainting.
- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heart beat, face swelling or breathing problems.
- Signs of a **stroke**, such as sudden onset of: severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain or shortness of breath.
- **Seizures or loss of consciousness.**
- **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
- Severe **skin reaction** where you have had radiation.
- **Muscle weakness.**
- **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 **kidney problems** such as lower back or side pain, swelling of feet or lower legs.
- Signs of **anemia** such as unusual tiredness or weakness.
- **Severe abdominal or stomach cramping or pain.**
- Signs of **lung problems** such as difficulty breathing or shortness of breath.
- **Skin rash** or itching.

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.
- Changes in fingernails or toenails.
- Heartburn; mild to moderate abdominal or stomach pain.
- Easy bruising or minor bleeding.
- Redness, swelling, pain or sores where the needle was placed.
- Ringing in your ears or hearing problems.
- Numbness or tingling in feet or hands or painful leg cramps.
- 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: _____