

For the Patient: GIGAVRAMT
**Other Names: Second-Line Therapy for
Metastatic or Locally Advanced Gastric or
Gastroesophageal Junction Cancer Using
Weekly PACLitaxel and Ramucirumab**

GI = Gastrointestinal
GAV= Gastric (stomach), **A**dvanced
RAM= Ramucirumab
T = Paclitaxel

ABOUT THIS MEDICATION

What is this treatment used for?

- Ramucirumab and paclitaxel are drugs given to treat cancer of the stomach and stomach-oesophagus junction.

How does this treatment work?

- Ramucirumab and paclitaxel 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

How are these drugs given?

- Paclitaxel and ramucirumab are given directly into the vein (IV).
- You will receive paclitaxel once a week for three weeks (Days 1, 8 and 15) and ramucirumab on the first and third week (Days 1 and 15). They will be given to you at the clinic by the chemotherapy nurse. A one week rest period follows the three weeks of chemotherapy.
- This 4 week cycle or 28 day period of time is called a “cycle”. The cycles are repeated as long as you are benefiting from chemotherapy, and not having too many side effects, as determined by your oncologist.
- Treatments will last about **three hours** on days with paclitaxel and ramucirumab (Days 1 and 15). Treatments will last about **two hours** on days with paclitaxel only (Day 8). Your first treatment will probably take longer, as the nurse will review information on the chemotherapy drugs with you.

The calendar below shows how the medications are given each 4 week cycle.

C Y C L E	DATE	TREATMENT PLAN
		▶ Day 1 → ramucirumab IV x 1 day → paclitaxel IV x 1 day
		▶ Day 8 → paclitaxel IV x 1 day
		▶ Day 15 → ramucirumab IV x 1 day → paclitaxel IV x 1 day
		▶ Day 22 → no treatment

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 before each day of treatment. A **urine test** and **blood pressure measurement** will be taken by a nurse before each ramucirumab treatment. The dose and timing of your chemotherapy may be changed based on your test results and/or other side effects.
- You will be given medication to help prevent an allergic reaction to paclitaxel and ramucirumab. This is usually given by the chemotherapy nurse, just before your treatment. The medications are given directly into the vein (IV).

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 paclitaxel and ramucirumab 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 commonly occur with paclitaxel and may sometimes occur with ramucirumab. Signs of an allergic reaction may include flushing, rash, dizziness, breathing problems, abdominal or back pain. This can occur immediately or several hours after receiving paclitaxel and/or ramucirumab and usually only with the first or second dose.	Tell your nurse if this happens while you are receiving paclitaxel or contact your oncologist immediately if this happens after you leave the clinic.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Paclitaxel 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.
Your white blood cells may decrease after your treatment. They usually return to normal 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: <ul style="list-style-type: none"> • 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 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.
Sore mouth may sometimes occur. 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.	<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 the 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.
Muscle or joint pain may commonly occur a few days after your treatment.	You may take acetaminophen (e.g. TYLENOL®) every 4 – 6 hours to a maximum of 4 g (4000 mg) per day. Tell your doctor if the pain interferes with your activity.
Nausea and vomiting may occur after your treatment. Most people have little or no nausea after ramucirumab.	You may 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. <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts • Try the ideas in <i>Practical Tips to Manage Nausea*</i>

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Fever may sometimes occur shortly after treatment with paclitaxel. Fever should last no longer than 24 hours.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g. TYLENOL®) every 4 – 6 hours to a maximum of 4 g (4000 mg) per day. • Fever (over 100°F or 38°C by an oral thermometer) which occurs more than a few days after treatment may be a sign of an infection. Report this to your doctor immediately. See “white blood cells” above under Serious Side Effects.
<p>Your platelets may decrease after your treatment. They usually return to normal before your next 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, to a maximum of 4 g (4000 mg) per day, but occasional use of ibuprofen may be acceptable.
<p>Minor bleeding, such as nosebleeds, may occur.</p>	<ul style="list-style-type: none"> • Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat. • Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes. • After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes. • Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped. • Get emergency help if a nosebleed lasts longer than 20 minutes.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Diarrhea may sometimes occur.	If diarrhea is a problem: <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>*
Constipation may sometimes occur.	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Food Choices to Manage Constipation</i>.*
Tiredness and lack of energy may commonly occur.	<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>*
Hair loss may occur from paclitaxel. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. Hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change.	<ul style="list-style-type: none"> • Refer to <i>Resources for hair loss and appearance changes</i>.* You may also want to: <ul style="list-style-type: none"> • 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.
Numbness or tingling of the fingers or toes may occur. This will slowly return to normal once your treatments are over. This may take several months.	<ul style="list-style-type: none"> • Be careful when handling items that are sharp, hot or cold. • Tell your doctor at your next visit, especially if you have trouble with buttons, writing, or picking up small objects.
Headache may rarely occur.	<ul style="list-style-type: none"> • Take acetaminophen (e.g. TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Skin rashes may sometimes occur.	If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
Loss of appetite may occur.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> * for food ideas to help with decreased appetite.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem: <ul style="list-style-type: none"> • Elevate your feet when sitting. • Avoid tight clothing.

*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 paclitaxel or ramucirumab before starting this treatment.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of treatment.

- Paclitaxel and ramucirumab 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 three months after your last ramucirumab treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment and for three months after your last ramucirumab treatment.
- If you are planning to have **surgery**, consult with your oncologist as ramucirumab should be stopped until recovery to lower the risk of bleeding and to prevent problems with wound healing after surgery.
- Tell doctors, dentist, and other health professionals that you are being treated with paclitaxel and ramucirumab before you receive any treatment from them.

Medication Interactions:

- Other drugs such as warfarin (COUMADIN®), disulfiram (ANTABUSE®) and metronidazole (FLAGYL®) may interact with paclitaxel.
- 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 **allergic reaction** soon after a treatment including dizziness, fast heart beat, face swelling, abdominal pain 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, productive cough (coughing up thick or green sputum); cloudy or foul smelling 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.
- 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.
- 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 **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.
- **Seizures** or **loss of consciousness** with or without **confusion**, **headache**, or changes in **eyesight**.
- Persistent bleeding, such as **nosebleeds** lasting more than 20 minutes.
- Sudden **abdominal pain**.

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

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- **Sores** that do not heal or are slow to heal.

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

- Uncontrolled nausea, vomiting, or diarrhea.
- Easy bruising, minor bleeding, or nosebleeds.
- Taste changes may occur.
- Headache 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, tongue, mouth, or throat.
- Nail changes.
- Abdominal discomfort including pain, bloating, or cramping.
- Skin rash or itching.
- Skin irritation where you may have had radiation treatments.
- Changes in vision, hearing loss, ringing in the ears, or dizziness.

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: _____