

For the Patient: **GIGAVTT**

Other Names: Third- or Later-Line Therapy of Advanced Gastroesophageal Carcinoma Using Trifluridine-Tipiracil

GI = **G**astro**I**ntestinal
G = **G**astric
AV = **A**d**V**anced
T = **T**rifluridine
T = **T**ipiracil

ABOUT THIS MEDICATION

What are these drugs used for?

- Trifluridine-tipiracil (trye flure' i deen – tye pir' a sil) is an oral drug treatment given as therapy to treat advanced gastric or gastroesophageal cancer.

How do these drugs work?

- Trifluridine-tipiracil interferes with DNA preventing cell proliferation. Tipiracil enhances the oral availability of trifluridine by inhibiting its rapid degradation and subsequent first-pass metabolism.

INTENDED BENEFITS

- Trifluridine-tipiracil is given to destroy and/or limit the growth of cancer cells.
- This treatment may improve your current symptoms, and delay or prevent the onset of new symptoms.

TREATMENT SUMMARY

How is this drug given?

- Trifluridine-tipiracil is taken by mouth twice daily, about 12 hours apart. You may be given tablets of more than one strength to make the right dose. Trifluridine-tipiracil should be taken with food.

What will happen when I get my drugs?

- A blood test is done before each treatment cycle.
- Your oncologist will assess whether you are to proceed with treatment, then write a prescription for the pharmacy.
- The dose and timing of your chemotherapy may change 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.

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

SIDE EFFECTS	MANAGEMENT
<p>Nausea and vomiting may occur while you are taking trifluridine-tipiracil. Most people have little or no nausea.</p>	<p>You may be given a prescription for antinausea drug(s) to take 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 fluids. • Eat and drink often in small amounts. <p>Try the ideas in <i>Practical Tips to Manage Nausea</i>.*</p>
<p>Fever may sometimes occur.</p>	<p>Fever (over 100°F or 38°C by an oral thermometer) may be a sign of an infection. Report this to your doctor immediately.</p>
<p>Diarrhea may sometimes occur.</p>	<ul style="list-style-type: none"> • If diarrhea is a problem: • 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>.* <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 trifluridine-tipiracil dose.</p>
<p>Your white blood cells may decrease. 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. • Avoid crowds and people who are sick. • Stop taking trifluridine-tipiracil and 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.
<p>Your platelets may decrease. 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.

	<ul style="list-style-type: none"> 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). <p>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>
Loss of appetite sometimes occurs.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
Tiredness and lack of energy may sometimes 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>Fatigue/Tiredness – Patient Handout</i>.*
Hair loss is rare with trifluridine-tipiracil. If you lose hair, it will grow back once you stop treatment with trifluridine-tipiracil. Colour and texture may change.	If hair loss is a problem, refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout</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 trifluridine-tipiracil before taking trifluridine-tipiracil.
- It is important to take trifluridine-tipiracil exactly as directed by your doctor. Make sure you understand the directions. You may be given tablets of more than one strength to make the right dose.
- Take** trifluridine-tipiracil with food. Trifluridine-tipiracil is usually taken twice daily, about 12 hours apart, with equal numbers of tablets taken at each dose.
- If you **miss a dose** of trifluridine-tipiracil, skip the missed dose and go back to your usual dosing times.
- If you **vomit** the dose of trifluridine-tipiracil, do not take a second dose. Skip the missed dose and go back to your usual dosing times. Let your doctor know as a medication to prevent nausea may be required for future doses.
- Other drugs may **interact** with trifluridine-tipiracil. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of trifluridine-tipiracil.
- Trifluridine-tipiracil may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with trifluridine-tipiracil and for at least 6 months after the last dose. Tell your doctor right away if you or your partner becomes

pregnant. Do not breastfeed during treatment and for at least 1 day after the last dose.

- **Store** trifluridine-tipiracil tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- **Tell** doctors, dentists, and other health professionals that you are being treated with trifluridine-tipiracil before you receive any treatment from them.

THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING TRIFLURIDINE-TIPIRACIL 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), 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 **lung problems** such new or worsening cough, chest pain, shortness of breath, or difficulty in breathing.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.

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

- Signs of **anemia** such as unusual tiredness or weakness

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

- Abdominal pain.
- Muscle or joint pain or muscle weakness.
- Uncontrolled nausea, vomiting, or diarrhea.
- Numbness or tingling in feet or hands.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Skin rash, dry skin, or itchiness.
- Feelings of anxiety (nervousness or worry) that is not usual for you.
- Taste changes.
- Heartburn or indigestion.
- Dizziness.
- Nosebleeds

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: _____