

For the Patient: Regorafenib
Other names: **STIVARGA®**

- **Regorafenib** (re" goe raf' e nib) is a drug that is used to treat some types of cancer. It is a tablet that you take by mouth.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to regorafenib or sorafenib before taking regorafenib.
- **Blood tests** and **blood pressure measurements** may be taken regularly during treatment. The dose and timing of your regorafenib may be changed based on the test results and/or other side effects.
- It is important to **take** regorafenib exactly as directed by your doctor. Make sure you understand the directions.
- **Take** regorafenib with food, preferably after a small low-fat meal or snack.
- If you **miss a dose** of regorafenib, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- If you **vomit** the dose of regorafenib within 30 minutes of taking it, repeat the dose. Let your doctor know as a medication to prevent nausea may be required for future doses.
- Other drugs such as ketoconazole (NIZORAL®), warfarin (COUMADIN®), and rifampin (RIFADIN®) may **interact** with regorafenib. 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 or stop taking any other drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of regorafenib.
- Regorafenib may cause **sterility** in men and women. If you plan to have children, discuss this with your doctor before being treated with regorafenib.
- Regorafenib may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with regorafenib and for 8 weeks after the last dose of regorafenib. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.

- **Store** regorafenib tablets out of the reach of children, at room temperature, away from heat, light, and moisture. Keep the bottle tightly closed and keep the desiccant in the bottle. Once the bottle is opened, the remaining regorafenib tablets must be discarded after **7 weeks**.
- **Tell** doctors, dentists, and other health professionals that you are being treated with regorafenib before you receive any treatment from them.
- If you are planning to have **surgery**, you should stop taking regorafenib 2 weeks prior to surgery. Do not restart regorafenib until the surgical wound is fully healed. This helps to lower the risk of bleeding and may prevent problems with wound healing after surgery.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur. Most people have little or no nausea.	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. <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Food Choices to Help Control Nausea</i>.*
Skin rashes may sometimes occur.	If very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
Fever may sometimes occur.	<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. • If you have fever (over 100°F or 38°C by an oral thermometer) plus another sign of infection, call your doctor immediately. Other signs of infection include chills, cough, or burning when you pass urine.
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 Ideas to Help Manage Diarrhea</i>.*

SIDE EFFECTS	MANAGEMENT
Constipation may sometimes occur.	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Suggestions for Dealing with Constipation</i>.*
High blood pressure commonly occurs. This can happen very quickly after starting treatment.	<p>Your blood pressure will be checked during your visits to your doctor.</p> <ul style="list-style-type: none"> • You may be asked to check your blood pressure frequently between visits. • Your doctor may give you medication if your blood pressure is high. • Tell your doctor if you are already on blood pressure medication. Your doctor may have to adjust your dose.
Your platelets may decrease during your treatment. They usually 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, to a maximum of 4 g (4000 mg) per day.
Sore mouth may sometimes occur a few days after 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.	<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>.*

SIDE EFFECTS	MANAGEMENT
<p>Hand-foot skin reaction commonly occurs during regorafenib 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. • Avoid tight-fitting jewellery. • Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. • Apply a sunscreen with an SPF (sun protection factor) of at least 30. • Apply lanolin-containing creams (e.g., BAG BALM®, UDDERLY SMOOTH®) to hands and feet, liberally and often. • Tell your cancer doctor or your nurse at the next visit if you have any signs of hand-foot skin reaction as your dose may need to be changed.
<p>Headache may sometimes occur.</p>	<p>Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.</p>
<p>Muscle pain or stiffness may sometimes occur.</p>	<p>You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your doctor if the pain interferes with your activity.</p>
<p>Loss of appetite and weight loss may sometimes occur.</p>	<p>Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i>.*</p>
<p>Tiredness and lack of energy commonly occur.</p>	<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 to Energy Savings: Helping People with Cancer Handle Fatigue</i>.*
<p>Hair loss sometimes occurs with regorafenib.</p>	<p>If hair loss is a problem, refer to <i>For the Patient: Hair Loss Due to Chemotherapy</i>.*</p>

*Please ask your chemotherapy nurse or pharmacist for a copy.

STOP TAKING REGORAFENIB 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 **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red

