

**Care Team Contact Information:**

**Pharmacy Contact Information:**

**Diagnosis:** \_\_\_\_\_

- This treatment is often used for colon or rectal cancer, liver cancer, and a rare stomach, bowel, or esophagus cancer called GIST (gastrointestinal stromal tumors). It may also be used for other reasons.

**Goal of Treatment:**

- Treatment may continue until it no longer works or until side effects are no longer controlled.

## Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Regorafenib (REH-goh-RA-feh-nib) Stivarga (stih-VAR-guh)	Slows down or stops the growth of cancer cells by blocking specific proteins involved in tumor growth and the formation of blood vessels.	Tablets taken by mouth.

**Treatment Administration and Schedule:** Regorafenib is usually taken 1 time a day for 21 days (3 weeks) and then stop for 7 days (1 week). Treatment is typically repeated every 4 weeks. This length of time is called a "cycle".

### Your regorafenib dosing instructions:

- Regorafenib comes in 1 tablet strength: 40 mg. Your care team will tell you how many tablets to take each day.
- Swallow regorafenib tablets whole with water following a low-fat meal.
- Take regorafenib at the same time each day following a low-fat meal that contains less than 600 calories and less than 30% fat.
  - Examples of a low-fat meal:
    - 4 ounces of 1% low-fat cottage cheese, 1 English muffin with 1 tablespoon of fat-free butter, 1 tablespoon of jam, and 8 ounces of apple juice
    - 1 cup cooked pasta,  $\frac{1}{2}$  cup meatless marinara sauce, 1.5 cups of vegetable salad, and 1 tablespoon oil/vinegar salad dressing
- If you miss a dose, take it as soon as you remember on that day but do not take two doses on the same day. Do not take another dose if you vomit.
- If you take too much regorafenib, call your care team or go to the nearest hospital emergency room right away.

## Treatment Administration and Schedule (Continued)

Treatment Name	Cycle 1, Days																					Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22-28
Regorafenib	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

## Storage and Handling of Regorafenib

- Store regorafenib at room temperature at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep regorafenib in the bottle that it comes in. Do not put regorafenib tablets in a daily or weekly pill box.
- The regorafenib bottle contains a desiccant to help keep your medicine dry. Keep the desiccant in the bottle.
- Keep the bottle of regorafenib tightly closed.
- People who are or may become pregnant should wear gloves when handling regorafenib.
- Keep regorafenib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused regorafenib. Safely dispose of any unused regorafenib 7 weeks after opening the bottle.

**Appointments:** Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

## Supportive Care to Prevent and Treat Side Effects

Description		Supportive Care Taken at Home
To help prevent or treat nausea and vomiting		
To help treat diarrhea (loose and/or urgent bowel movements)		
To help prevent or treat pain or discomfort in hands and/or feet		
Other		

## Common Side Effects

Side Effect	Important Information
Liver Problems (Boxed Warning)	<p>Description: Regorafenib can cause liver problems which can be serious and sometimes lead to death. Your care team will do blood tests to check your liver function before you start taking regorafenib and during your treatment with regorafenib to check for liver problems.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Yellowing of your skin or the whites of your eyes</li> <li>Severe nausea or vomiting</li> <li>Pain on the right side of your stomach area (abdomen)</li> <li>Dark “tea-colored” urine</li> <li>Bleeding or bruising more easily than normal</li> </ul>
Infection	<p>Description: Regorafenib may lead to a higher risk of infections especially of the urinary tract, nose, throat and lung. Regorafenib may also lead to a higher risk of fungal infections of the mucous membrane, skin or the body.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Wash your hands and bathe regularly.</li> <li>Avoid crowded places.</li> <li>Stay away from people who are sick.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Fever of 100.4°F (38°C) or higher</li> <li>Severe cough with or without an increase in mucus (sputum) production</li> <li>Severe sore throat</li> <li>Shortness of breath</li> <li>Burning or pain when urinating</li> <li>Unusual vaginal discharge or irritation</li> <li>Redness, swelling or pain in any part of the body</li> </ul>
Low Platelet Count	<p>Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you are at a higher risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Blow your nose gently and avoid picking it.</li> <li>Brush your teeth gently with a soft toothbrush and maintain good oral hygiene.</li> <li>Use an electric razor for shaving and a nail file instead of nail clippers.</li> <li>Avoid over-the-counter medications that may increase the risk of bleeding, such as NSAIDs.</li> <li>Talk with your care team or dentist before medical or dental procedures, as you may need to pause your treatment.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Nosebleed lasting over 5 minutes despite pressure</li> <li>Cut that continues to bleed</li> <li>Significant gum bleeding when flossing or brushing</li> <li>Severe headaches</li> <li>Blood in your urine or stool</li> <li>Blood in your spit after a cough</li> </ul>

Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb)	<p>Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you may feel weak, tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Get 7 to 8 hours of sleep each night.</li> <li>Avoid operating heavy machinery when tired.</li> <li>Balance work and rest, staying active but resting when needed.</li> </ul>	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Shortness of breath</li> <li>Dizziness</li> <li>Fast or abnormal heartbeats</li> <li>Severe headache</li> </ul>
Fatigue	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you.</li> <li>Ask your family and friends for help with daily tasks and emotional support.</li> <li>Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good.</li> <li>Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep.</li> <li>Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents.</li> </ul>	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Tiredness that affects your daily life</li> <li>Tiredness all the time, and it doesn't get better with rest</li> <li>Dizziness and weakness, along with being tired</li> </ul>
High Blood Pressure	<p>Description: High blood pressure happens when the pressure of blood against the walls of your arteries is too high, and it can lead to heart disease and stroke. It's important to check your blood pressure regularly. Your care team might give you medicine or change your treatment if needed.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Exercise regularly, control your weight, and limit alcohol and sodium consumption.</li> <li>If you are already being treated for high blood pressure, your care team may change your blood pressure medicine.</li> <li>Your care team may ask you to track your blood pressure.</li> </ul>	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Severe headache</li> <li>Shortness of breath</li> <li>Nose bleeds</li> </ul>
Stomach-Area (Abdominal) Pain	<p>Description: Abdominal pain is when you feel discomfort or pain in the belly area.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Severe abdominal pain</li> </ul>	

Low Appetite	<p>Description: Low appetite means you don't feel like eating as much as usual. It's important to get enough nutrition and maintain a healthy weight because protein and calories are essential for recovery and feeling good.</p> <p>Recommendations:</p> <ul style="list-style-type: none"><li>• Be as active as possible. Do some physical activity before a meal. Before starting an exercise program, talk with your care team.</li><li>• Take note of the times during the day when your appetite is best. Do not limit food when your appetite is good. Eat your largest meal when you feel the hungriest, whether it is breakfast, lunch, or dinner.</li><li>• Eat 5-6 small meals per day and snack anytime.</li><li>• Choose foods high in protein, such as beans, chicken, fish, meat, yogurt, tofu, and eggs. During meals, eat high-protein foods first.</li><li>• Choose foods that are high in calories. Do not select foods that are labeled "low-fat," "fat-free" or "diet."</li><li>• If you feel full quickly when eating, do not drink any liquids 30 minutes before a meal so you have more room for solid food. Then, drink liquids between meals. Choose liquids with extra calories, not diet drinks.</li><li>• Eat a bedtime snack. Choose something easy to digest, such as peanut butter and crackers. If you tend to experience reflux or heartburn, eat at least an hour before lying down.</li><li>• If food is not appealing, try a nutritious beverage, such as a high-protein shake or smoothie, instead of solid food.</li><li>• Ask your healthcare team to recommend a liquid nutrition supplement. Add a scoop of protein powder, yogurt, or ice cream for added protein and calories.</li></ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"><li>• Severe weight loss</li><li>• Weight loss with severe fatigue or weakness</li></ul>
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Mouth Irritation and Sores	<p>Description: This treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Rinse your mouth after meals and at bedtime, and more often if sores develop.</li> <li>Brush your teeth with a soft toothbrush or cotton swab after meals.</li> <li>Use a mild, non-alcohol mouth rinse at least four times daily (after meals and at bedtime). A simple mixture is 1/8 teaspoon salt and 1/4 teaspoon baking soda in 8 ounces of warm water.</li> <li>Avoid acidic, hot, spicy, or rough foods and drinks that may irritate your mouth.</li> <li>If you have mouth sores, avoid tobacco, alcohol, and alcohol-based mouth washes.</li> <li>Your care team may prescribe medicine for these symptoms.</li> </ul>	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Pain or sores in your mouth or throat</li> </ul>
Diarrhea	<p>Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Keep track of how many times you go to the bathroom each day.</li> <li>Drink 8 to 10 glasses of water or other fluids every day, unless your doctor tells you otherwise.</li> <li>Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast.</li> <li>Stay away from foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods.</li> <li>Your care team may recommend medicine (such as loperamide) for diarrhea.</li> </ul>	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>4 or more bowel movements than normal in 24 hours</li> <li>Dizziness or lightheadedness while having diarrhea</li> <li>Bloody diarrhea</li> </ul>
Voice Changes or Hoarseness	<p>Description: Hoarseness is when you have a weak, rough, or harsh voice.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Drink plenty of water and avoiding irritants (e.g., dust, smoke, alcohol, industrial chemicals).</li> <li>Write things down to give your voice a break.</li> <li>Avoid shouting or whispering</li> </ul>	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Severe hoarseness</li> <li>Hoarseness accompanied by throat pain</li> </ul>

Hand-Foot Skin Reaction	<p>Description: Hand-Foot Skin Reaction causes dryness, thickening, calluses, blisters, or cracking of the skin on the palms of your hands and soles of your feet.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Keep hands and feet moisturized with a non-scented moisturizing cream.</li> <li>Applying urea 10% or 20% cream twice daily to the affected area may be helpful.</li> <li>Avoid exposure to hot water on the hands and feet in showers or baths that may dry out the skin or by doing dishes.</li> <li>Avoid tight-fitting shoes or socks.</li> <li>Avoid excess rubbing on hands and feet unless putting on lotion.</li> <li>Wear gloves when working with your hands.</li> </ul>	Talk to your care team if you have:	<ul style="list-style-type: none"> <li>Painful blisters or calluses</li> </ul>
Rash or Itchy Skin	<p>Description: Rash or itching skin can cause symptoms like redness, swelling, and varying bumps, such as small red spots, welts, or patches.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Keep your skin moisturized with creams or lotions to reduce rash and itchiness; wear loose-fitting clothing.</li> <li>Avoid perfumes and colognes, as they may worsen rash symptoms.</li> <li>Limit time spent in heat to prevent worsening symptoms.</li> <li>Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn.</li> <li>Wear long-sleeved clothing with UV protection and broad-brimmed hats.</li> <li>Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as directed.</li> <li>Use lip balm that contains at least SPF 30.</li> <li>Avoid tanning beds.</li> <li>Your care team may recommend using over-the-counter antihistamines or topical creams.</li> </ul>	Talk to your care team if you have:	<ul style="list-style-type: none"> <li>Rash or itching that continues to worsen</li> </ul>

## Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Severe Bleeding	<ul style="list-style-type: none"> <li>Vomiting blood or if your vomit looks like coffee-grounds</li> <li>Pink or brown urine</li> <li>Red or black (looks like tar) stools</li> <li>Coughing up blood or blood clots</li> <li>Menstrual bleeding that is heavier than normal</li> </ul>	<ul style="list-style-type: none"> <li>Unusual vaginal bleeding</li> <li>Nose bleeds that happen often</li> <li>Bruising</li> <li>Lightheadedness</li> </ul>
A Tear in Your Stomach or Intestinal Wall (Bowel Perforation)	<ul style="list-style-type: none"> <li>Severe pain in your stomach-area (abdomen)</li> <li>Swelling of the abdomen</li> <li>Fever</li> <li>Chills</li> </ul>	<ul style="list-style-type: none"> <li>Nausea</li> <li>Vomiting</li> <li>Dehydration</li> </ul>
Heart Problems	<ul style="list-style-type: none"> <li>New or worsening chest discomfort, including pain or pressure</li> <li>Breaking out in a cold sweat</li> </ul>	<ul style="list-style-type: none"> <li>Pain in your arms, back, neck, or jaw</li> <li>Feeling lightheaded or dizzy</li> </ul>
Brain Swelling	<ul style="list-style-type: none"> <li>Headache</li> <li>Changes in the way you think</li> <li>Blurry vision or loss of vision</li> </ul>	<ul style="list-style-type: none"> <li>Confusion</li> <li>Seizures</li> </ul>

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.  
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**

## Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
  - If you are able to become pregnant, take a pregnancy test before starting treatment.
  - Use an effective method of birth control during treatment and for 2 months after your last dose.
  - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment and for 2 months after your last dose.
- Do NOT breastfeed** during treatment and 2 weeks after your last dose.

## Additional Information

- **Tell your care team about all the medicines you take.**  
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Avoid drinking grapefruit juice and taking St. John's Wort** during treatment with regorafenib. These can affect the way regorafenib works.
- **Risk of developing protein in your urine.** Your care team may check your urine for protein before and during treatment and may adjust or stop your treatment if protein is found.
- **Risk of wound healing problems.** Wounds may not heal properly during regorafenib treatment. Tell your care team if you plan to have any surgery before starting or during treatment.
  - You should stop taking regorafenib at least 2 weeks before planned surgery.
  - Your care team should tell you when you may start taking regorafenib again after surgery.
- **This Patient Education Sheet may not describe all possible side effects.**  
Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

## Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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PES-214