



Regorafenib (Stivarga®)

Pronounce: re-goe-RAF-e-nib

Classification: Tyrosine Kinase Inhibitor

About Regorafenib (Stivarga®)

Regorafenib is a type of targeted therapy called a tyrosine kinase inhibitor. A kinase is an enzyme that helps with cell growth. There are many types of kinases that control different phases of cell growth. Regorafenib targets several different receptors, which, in turn, blocks tumor growth and angiogenesis (the forming of a blood supply to the tumor).

How to Take Regorafenib

Regorafenib comes as a tablet to be taken by mouth. Your dose and how often you take this medication will be decided by your healthcare provider. Swallow the tablet whole after a low-fat meal (containing less than 600 calories and less than 30% fat). Talk with your provider about low-fat meal options for you. Do not break, chew or crush the tablets. If you miss a dose, take it as soon as you remember on that day. Do not take two doses in one day to make up a missed dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, ketoconazole, rifampin, carbamazepine, phenobarbital, phenytoin, St. John's wort, and many anti-fungal medications. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your pharmacist). This medication should not be stored in a pillbox. Do not remove the desiccant packet from the container, as this keeps the environment in the bottle dry. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Regorafenib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, are also available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Regorafenib

There are a number of things you can do to manage the side effects of regorafenib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Liver Toxicity

This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen, as these can be signs of liver toxicity.

Proteinuria

This medication can cause an increase in the amounts of protein in your urine. Your healthcare team will monitor your kidney function and protein in your urine throughout treatment with this medication.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Muscle or Joint Pain/Aches and Abdominal Pain

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Hand Foot Syndrome

Hand foot syndrome (HFS) is a skin reaction that appears on the palms of the hands and/or the soles of the feet, as a result of certain chemotherapy agents being absorbed by the skin cells. HFS can begin as a mild tingling, numbness, pins-and-needles feeling, redness or pain or swelling of the hands and/or feet. This can then progress to painful swelling, blistering or peeling skin that can interfere with your ability to do normal activities. Be sure to let your oncology team know right away if you notice these symptoms, as they may need to adjust the chemotherapy dose or take a break to allow the skin to heal. Some tips to help prevent HFS include:

- Keep hands and feet clean and dry.
- Avoid tight shoes or socks.
- Avoid activities that put pressure on the palms or soles for 1 week after treatment.
- Apply an alcohol-free moisturizer liberally and often. (Avoid moisturizers with perfumes or scents)
- Avoid very hot water for baths and showers.

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

This medication can cause life threatening infections, with or without a decrease in white blood cell counts.

White blood cells (WBC) are important for fighting infection. While receiving treatment, your **WBC count can**

drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

High Blood Pressure

This medication can cause high blood pressure (hypertension). Patients should have their blood pressure checked regularly during therapy. Any hypertension should be treated appropriately. If hypertension cannot be controlled, the medication may be stopped. Report any headaches, vision changes or dizziness to your oncology care team.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the **count is low** you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the **red cell count is low**, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Diarrhea

Your oncology care team can recommend medications to relieve **diarrhea**. Also, try eating **low-fiber**, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Decrease in Appetite

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (potassium, magnesium, calcium, etc.) in your body. Your levels will be monitored with blood tests. If your levels become too low, your care team may prescribe certain electrolytes to be given by IV or taken by mouth. Do not take any supplements without first talking with your care team.

Mouth Ulcers (Mucositis)

Certain cancer treatments can cause [sores or soreness in your mouth](#) and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing [regular mouth care](#) can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

Dysphonia

This medication can cause changes to your voice, including hoarseness.

Pancreas Problems

Bloating, indigestion, fatty stools, loss of appetite, sweating, abdominal (belly) pain, and weight loss can all be symptoms of pancreatitis (inflammation of the pancreas). Call your care provider if you have any of these symptoms. Your provider may monitor certain labs during treatment, including lipase and amylase.

Rash

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They

can give you more tips on [caring for your skin](#).

Fever

Fever can be a side effect of this medication. Call your provider for a temperature of 100.4°F or 38°C or greater.

Loss or Thinning of Scalp and Body Hair (Alopecia)

Your hair may become [thin, brittle, or may fall out](#). This often begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage [nausea and vomiting](#). In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Important but Less Common Side Effects

- **Hemorrhage (Bleeding):** Serious bleeding has occurred in patients treated with this medication. People who have a history of serious bleeding should not take this medication. If you take aspirin, non-steroidal anti-inflammatory medications (NSAIDs such as Motrin, ibuprofen, naproxen) or other medication that affects blood clotting, let your healthcare provider know. Signs of bleeding can include: blood in the stool or dark, tarry stools, coughing up or vomiting blood, or vomit that looks like coffee grounds. While some bleeding, such as a nosebleed, may not seem like much of a concern, you should call your healthcare team right away if you develop bleeding of any sort. Your provider may perform blood tests to monitor your INR levels, which tell how quickly your blood clots.
- **GI Tear or Fistula:** This medication can cause a tear in the intestinal wall, also called a gastrointestinal (GI) perforation, or a fistula (whole connecting two parts of your GI tract). Signs of this can include: new or worsening pain in the abdomen, new abdominal swelling, chills, fever, constipation, nausea or vomiting. If you have any of these, contact your provider right away or go to the emergency room.
- **Posterior Reversible Encephalopathy Syndrome (PRES):** In rare cases, this medication has caused a neurological disorder called posterior reversible encephalopathy syndrome (PRES), also called reversible posterior leukoencephalopathy (RPLS). Symptoms of PRES/RPLS include headache, seizure, lethargy, confusion, blindness and other visual and neurological disturbances. Report any of these symptoms to your healthcare team right away.
- **Heart Attack:** In studies, some patients experienced heart attack and chest pain. If you have symptoms of a heart attack, go to an emergency room right away. Symptoms can include: chest pain or pressure, pain in your arm, back, neck or jaw, shortness of breath or dizziness.
- **Wound Healing:** This medication can lead to slower or incomplete wound healing, such as a surgical wound not healing or staying closed. Be sure to inform the team performing the surgical procedure that you are taking everolimus. You should also inform your oncology team that a surgical procedure is planned. You will need to stop taking the medication 2 weeks prior to surgery. You should not restart the medication for 2 weeks after your surgery or until any surgical incision has adequately healed. If you have a surgical wound that has not healed or begins to have signs of infection (redness, swelling, warmth), report this to your healthcare team.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 2 months after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication or for 2 weeks after your last dose.

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