

Regorafenib (Stivarga)

About This Drug

Regorafenib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Tiredness and weakness
- Fever
- Infection
- Changes in your liver function
- Pain
- Voice changes/hoarseness
- Decreased appetite (decreased hunger)
- Weight loss
- Rash
- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.
- High blood pressure

Note: Each of the side effects above was reported in 20% or greater of patients treated with regorafenib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Risk of severe and life-threatening infections
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your doctor know right away.**
- Changes in your heart function and risk of heart attack



- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Perforation or fistula - an abnormal hole in your stomach, intestine, esophagus, or other organ, which can be life-threatening.
- Changes in your liver function, which can cause liver failure and be life-threatening
- Severe allergic skin reaction. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Severe high blood pressure
- Slow wound healing

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- Regorafenib may cause slow wound healing. It should not be given within at least 2 weeks of planned surgery and for at least 2 weeks and until adequate wound healing following major surgery. If you must have emergency surgery, or have an accident that results in a wound, tell the doctor that you are on regorafenib.

How to Take Your Medication

- Swallow the medicine whole with water after a low-fat meal (less than 600 calories and less than 30% fat).
- Take this medicine at the same time each day.
- **Missed dose:** If you miss a dose, take it as soon as you think about it on that day. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature. Do not remove the desiccant and keep bottle tightly closed after first opening. Discard any remaining medicine 7 weeks after opening the bottle.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).



- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with nausea, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages,
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Avoid sun exposure and apply sunscreen routinely when outdoors.

Food and Drug Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of regorafenib in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with regorafenib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking regorafenib as this may lower the levels of the drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:



- Fever of 100.4° F (38° C) or higher
- Chills
- Confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Blurry vision or changes in your eyesight
- Extreme tiredness and/or coma
- Tiredness or weakness that interferes with your daily activities
- Headache that does not go away
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Severe abdominal pain that does not go away
- Difficulty swallowing
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling in your hands and/or feet
- Pain that does not go away or is not relieved by prescribed medicine
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 2 months after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 2 months after



stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.

- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment and for 2 weeks after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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