

ORAL CANCER TREATMENT EDUCATION



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REGORAFENIB

Name of your medication

Generic name — regorafenib (REH-goh-RA-feh-nib)
Brand name — Stivarga® (stih-VAR-guh)

Common uses

Regorafenib is used to treat colorectal cancer, gastrointestinal stromal tumor, and hepatocellular carcinoma.
Regorafenib may also be used for other treatments.

Dose and schedule

Taking regorafenib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- ❑ Your dose may vary, but the usual dose of regorafenib is 160 milligrams (160 mg) to be taken by mouth at a scheduled time once a day for the first 21 days of each 28-day cycle.
- ❑ Regorafenib should be taken with water after a low-fat meal that contains less than 600 calories and less than 30% fat and at the same time each day. Two examples are (a) 1% low-fat cottage cheese (4 ounces), 1 English muffin with 1 tablespoon of fat-free butter, 1 tablespoon of jam, and 8 ounces of apple juice and (b) 1 cup of cooked pasta, 1/2 cup of meatless marinara sauce, 1.5 cups of vegetable salad, and 1 tablespoon of oil/vinegar salad dressing.
- ❑ Regorafenib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow regorafenib, talk to your care provider or pharmacist for possible options.
- ❑ If you miss a dose of regorafenib, take it as soon as you remember on that day. Do not take two doses on the same day to make up for a missed dose.
- ❑ If you need to have surgery, tell your care provider you are taking regorafenib. Regorafenib may need to be stopped until your wound heals after some surgeries.

Drug and food interactions

- ❑ Regorafenib has many drug interactions. Inform your care team of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- ❑ Grapefruit or grapefruit juice may interact with regorafenib; avoid eating or drinking these during treatment with regorafenib.
- ❑ Talk with your care team or pharmacist before receiving any vaccines.

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Storage and handling

Handle regorafenib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store regorafenib at room temperature (68°F–77°F) in a dry location away from light.
- Keep regorafenib out of reach of children and pets.
- Leave regorafenib in the provided packaging until it is ready to be taken.
- Whenever possible, give regorafenib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the regorafenib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the regorafenib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is **not** recommended for use with regorafenib.
- If you have any unused regorafenib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of regorafenib.
- If you are traveling, put your regorafenib in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.
- Discard any unused tablets seven weeks after opening the bottle. Dispose of unused tablets in accordance with local requirements.

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Side Effects of Regorafenib

Below are common side effects that have been known to happen in about one third or more of patients taking regorafenib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored using a blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your healthcare provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
<p>Kidney damage</p>	<p>Your care provider will monitor your kidney function by checking the amount of protein in your urine.</p>
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • Low calcium levels • Low phosphate levels • Low sodium levels • High lipase levels • Low potassium levels • Increased INR levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Bleeding or bruising • Swelling of your legs or feet • Red- or brown-colored urine

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Possible Side Effect	Management
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed, too. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Decreased appetite or weight loss</p>	<p>Talk to your care provider if you notice a decrease in weight while taking this medication.</p> <p>When you do not feel like eating, try the following:</p> <ul style="list-style-type: none"> • Eat small frequent meals instead of three large meals each day. • Keep snacks nearby so you can eat when you feel hungry. • Take liquid nutritional supplements. • Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.
<p>Pain or discomfort in hands and/or feet</p>	<p>Hand-foot skin reaction (HFSR) appears on the palms of the hands and soles of the feet. It can appear as a rash, callus, or peeling skin, and the area has increased sensitivity to heat or a “pins and needles” sensation. Let your care provider know right away if you experience this side effect. To prevent HFSR, you can:</p> <ul style="list-style-type: none"> • Soak your feet in a water bath with Epsom salt and gently pumice any callused skin. • Exfoliate and keep hands and feet moisturized. • Avoid tight-fitting shoes or socks. • Use cushioning (i.e., gloves) when performing activities that increase pressure on the palms of your hands.

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Possible Side Effect	Management
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains). • Avoid foods that cause gas (e.g., broccoli, beans). • Avoid lactose-containing foods (e.g., yogurt, milk). • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently, and do not pick your nose. • Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include the following:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

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Possible Side Effect	Management
Mouth irritation or sores	<p>Practice good mouth care.</p> <ul style="list-style-type: none"> Rinse your mouth frequently. Brush your teeth with a soft toothbrush or cotton swab after meals. Use a mild nonalcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>
Increased blood pressure	<p>Routinely take your blood pressure. Record your blood pressure in a journal/diary and report these to your physician. Contact your healthcare provider for high blood pressure or if the following symptoms occur:</p> <ul style="list-style-type: none"> Headache Dizziness Chest pain Shortness of breath Fluid retention, weight gain, or swelling
Voice changes or hoarseness	<p>These changes are not permanent and should go away when you are not taking the medication.</p>
Rash or itchy skin	<ul style="list-style-type: none"> Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing. Avoid using perfumes and cologne as these products may increase rash symptoms. Avoid being in the heat for long periods of time. Your provider may recommend an over-the-counter antihistamine or a topical cream. Sunlight can make symptoms worse. Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV radiation occurs between 10am and 4pm. Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. Wear long-sleeved clothing with UV protection if possible. Wear broad-brimmed hats. Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
Abdominal pain	<p>Abdominal pain or discomfort may occur. Report any serious pain or symptoms to your care provider immediately.</p>
Pain	<ul style="list-style-type: none"> Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Stay as active as possible, but know that it is OK to rest as needed, too. Tell your care provider if pain interferes with your activity. If the pain bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.

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Serious side effects of regorafenib

- Seek medical attention right away if you have any chest pain or tightness.
- There is a low risk that you may develop a rare condition called posterior reversible leukoencephalopathy syndrome (PRES) while taking regorafenib. Seek care immediately if you have severe headaches, seizures, confusion, or changes in vision.
- Rarely, regorafenib can cause severe skin reactions, including Stevens-Johnson syndrome, which can be life-threatening. Seek emergency care if you have a severe rash or a rash on your mouth, eyes, or genitals.
- Regorafenib may rarely cause a tear or hole in your intestine, called bowel perforation. Speak to your care team right away if you have a high fever, or nausea, vomiting, or severe stomach pain.
- You may be at a higher risk of bleeding while taking regorafenib. Contact your care team if you notice frequent nose bleeds, blood in your stool, bleeding that occurs by itself without injury, or bleeding that will not stop after five minutes of pressure.
- Regorafenib can cause cuts or wounds to heal more slowly. Tell your care team if you have a wound that doesn't heal properly. Also tell your care team if you have planned surgery or dental procedure, as regorafenib should be stopped prior to your surgery. Your doctor may restart regorafenib after your surgical wound has healed.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Because regorafenib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take regorafenib, it is important to follow the instructions below every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or regorafenib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

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Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking regorafenib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 2 months after the last dose of regorafenib.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking regorafenib and for 2 weeks after the last dose of regorafenib.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about the process for obtaining your regorafenib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.stivarga-us.com

Product prescribing information: http://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf

Product resources: www.stivarga-us.com/useful-resources

Updated – January 9, 2024

Additional instructions

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Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. 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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