

MY STIVARGA® (regorafenib): IMPORTANT TIPS AND REMINDERS

COMMUNICATION WITH YOUR DOCTOR

- ✓ **CONTACT YOUR DOCTOR** as soon as you receive your STIVARGA to schedule your first appointment within the first week. **STAY IN TOUCH** with your doctor, especially during the first week of treatment
- ✓ **CALL YOUR DOCTOR** as soon as you suspect a potential side effect
- ✓ Your doctor or nurse will do blood tests to check your liver function before you start taking STIVARGA, as well as during your treatment with STIVARGA, to check for liver problems
- ✓ **YOUR DOCTOR CAN HELP YOU MANAGE SIDE EFFECTS**, for example, by lowering your dose or temporarily stopping treatment. If you experience serious side effects or continue to experience side effects, your doctor may permanently stop treatment

ABOUT DOSING

- ✓ Take STIVARGA **EXACTLY** as your healthcare provider tells you to
- ✓ Be sure you **UNDERSTAND YOUR DAILY DOSE** (ie, number of tablets each day) that your doctor has prescribed for you
- ✓ **REPEAT YOUR TREATMENT CYCLE** for as long as your healthcare provider tells you to
- ✓ If you miss a dose, **TAKE IT AS SOON AS YOU REMEMBER ON THE SAME DAY**
- ✓ Remember to take your tablets at the **SAME TIME EACH DAY**
- ✓ **DO NOT TAKE 2 DOSES ON THE SAME DAY** to make up for a missed dose from the previous day
- ✓ **AVOID DRINKING GRAPEFRUIT JUICE AND TAKING ST JOHN'S WORT** while taking STIVARGA, as they can affect the way STIVARGA works
- ✓ If you take too much STIVARGA, **CALL YOUR HEALTHCARE PROVIDER** or go to the nearest emergency room right away

ABOUT STORAGE

- ✓ Keep STIVARGA in its **ORIGINAL BOTTLE**, as it contains a special drying agent (called a desiccant) to keep your medicine dry. Do not put the tablets in a daily or weekly pill bottle
- ✓ You will need to remove the drying agent to get tablets from the bottle. **PUT IT BACK IN THE ORIGINAL BOTTLE** after getting your medicine
- ✓ Keep the bottle of STIVARGA **TIGHTLY CLOSED** and store at room temperature
- ✓ STIVARGA boxes contain multiple bottles. Open only **1 BOTTLE AT A TIME**
- ✓ Any unused STIVARGA tablets should be **SAFELY THROWN AWAY** 7 weeks after opening the bottle
- ✓ Keep STIVARGA and all medicines **OUT OF THE REACH OF CHILDREN**

Please see additional Important Safety Information on page 3 and click for full [Prescribing Information](#), including the Boxed Warning.

DOCTOR'S NAME

Phone

Email

NURSE'S NAME

Phone

Email

YOUR NEXT APPOINTMENT

Date

MM

DD

YY

Time

:

TAKING STIVARGA

YOUR ONCE-DAILY DOSE

Each day, take the number of tablets your doctor has marked

Week 1

40 mg

40 mg

40 mg

40 mg

Week 2

40 mg

40 mg

40 mg

40 mg

Week 3

40 mg

40 mg

40 mg

40 mg

Week 4

Take a break—start again next week

INDICATIONS

STIVARGA (regorafenib) is a prescription medicine used to treat adults with:

- colon or rectal cancer that has spread to other parts of the body and for which they have received previous treatment with certain chemotherapy medicines
- a rare stomach, bowel, or esophagus cancer called GIST (gastrointestinal stromal tumor) that cannot be treated with surgery or that has spread to other parts of the body and for which they have received previous treatment with certain medicines
- a type of liver cancer called hepatocellular carcinoma (HCC) in people who have been previously treated with sorafenib

It is not known if STIVARGA is safe and effective in children less than 18 years of age.

IMPORTANT SAFETY INFORMATION

STIVARGA (regorafenib) can cause severe liver problems, including increased blood ammonia, which can sometimes lead to death. Your healthcare provider will do blood tests to check your liver function before you start taking STIVARGA and during your treatment with STIVARGA to check for liver problems.


Stivarga®
(regorafenib) tablets

HELPING YOU PLAN YOUR LOW-FAT MEALS

STIVARGA® (regorafenib) should be taken with water at the same time each day after a low-fat meal containing <600 calories and <30% fat. The following sample meals are provided as a guide to help you understand what types of food would be considered part of a low-fat meal when taking your medication. Discuss with your doctor what other types of food you should eat throughout the day.

IF YOU TAKE STIVARGA AFTER BREAKFAST

	Sample Breakfast 1	Sample Breakfast 2	Sample Breakfast 3
	• Bran Flakes Cereal (¾ cup) • 1% Milk (1 cup) • Toasted White Bread (1 slice) • Fat-Free Butter (1 tablespoon) • Orange Juice (8 ounces)	• Instant Oatmeal Maple & Brown Sugar (1 package, prepared with water) • 1 Medium-Sized Banana (8") • Whole Wheat Bread (1 slice) • Fat-Free Butter (1 tablespoon) • Jam or Preserves (1 tablespoon) • Coffee (instant served with skim milk)	• 1% Low-Fat Cottage Cheese (4 ounces) • English Muffin (1) • Fat-Free Butter (1 tablespoon) • Jam or Preserves (1 tablespoon) • Apple Juice (8 ounces)
	Total Calories: 383 Total Fat: 10.1%	Total Calories: 411 Total Fat: 8.3%	Total Calories: 379 Total Fat: 5.9%

IF YOU TAKE STIVARGA AFTER LUNCH

	Sample Lunch 1	Sample Lunch 2	Sample Lunch 3
	• Turkey Breast Lunch Meat (2 slices) • Toasted White Bread (2 slices) • Mayonnaise (1 tablespoon) • Lettuce and Tomato (1 leaf/slice) • 1 Large Apple (4") • Cranberry Juice (8 ounces)	• Light Tuna Fish (canned in water) • Lettuce (½ cup Romaine, shredded) • Whole Wheat Bread (1 slice) • Crunchy Granola Bar (2 oat & honey bars) • Tea (8 ounces)	• Extra-Lean Sliced Ham (2 slices) • English Muffin (1) • Egg Substitute (1 cup, cooked in a pat of butter) • Carrot Sticks (4 ounces) • Water (8 ounces)
	Total Calories: 496 Total Fat: 23.6%	Total Calories: 457 Total Fat: 16.5%	Total Calories: 399 Total Fat: 14.9%

IF YOU TAKE STIVARGA AFTER DINNER

	Sample Dinner 1	Sample Dinner 2	Sample Dinner 3 (Vegetarian)
	• Chicken (½ boneless, skinless breast) • 1 Medium-Sized Baked Potato (with skin) • Fat-Free Butter (1 tablespoon) • Whole-Kernel Canned Corn (1 cup, drained) • Sparkling Water (8 ounces)	• Salmon (1 fillet, cooked in a pat of butter) • Brown Rice (¾ cup, cooked) • Broccoli (½ cup, no salt) • Unsweetened Iced Tea (8 ounces)	• Spaghetti (1 cup, cooked without added salt) • Meatless Marinara Sauce (½ cup) • Vegetable Salad (½ cup) • Salad Dressing—Oil and Vinegar (1 tablespoon)
	Total Calories: 408 Total Fat: 10.6%	Total Calories: 584 Total Fat: 25.3%	Total Calories: 435 Total Fat: 26.5%

Be sure to review calories, fat, and ingredients with your healthcare provider to ensure you are planning a low-fat meal that contains <600 calories and <30% fat.

WWW.CALORIECOUNT.COM

IMPORTANT SAFETY INFORMATION (CONTINUED)

Tell your healthcare provider right away if you get any of these signs or symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes (jaundice)
- pain on the upper right side of your stomach area (abdomen)
- nausea or vomiting
- loss of appetite
- light-colored stools (bowel movements)
- dark “tea-colored” urine
- severe headache or headaches that persist
- vision changes
- seizures
- feeling more tired than usual
- drowsiness
- trembling
- confusion
- memory loss or disorientation

Before taking STIVARGA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems in addition to liver cancer
- have bleeding problems
- have high blood pressure
- have heart problems or chest pain
- plan to have surgery or have had a recent surgery. You should stop taking STIVARGA at least 2 weeks before planned surgery
- are pregnant or plan to become pregnant. STIVARGA can harm your unborn baby.
 - Females should use effective birth control during treatment with STIVARGA and for 2 months after your final dose of STIVARGA. Tell your healthcare provider right away if you become pregnant during treatment with STIVARGA or within 2 months after your final dose of STIVARGA.
 - Males with female partners who can become pregnant should use effective birth control during treatment with STIVARGA and for 2 months after your final dose of STIVARGA.
- are breast-feeding or plan to breast-feed. It is not known if STIVARGA passes into your breast milk. Do not breastfeed during treatment with STIVARGA and for 2 weeks after your final dose of STIVARGA.

Tell your healthcare provider about all the prescription and over-the-counter medicines, vitamins, and herbal supplements you take. Avoid drinking grapefruit juice and taking St. John’s Wort while taking STIVARGA.

STIVARGA may cause **serious** side effects, including:

- **infection.** STIVARGA may lead to a higher risk of infections especially of the urinary tract, nose, throat and lung. STIVARGA may lead to a higher risk of fungal infections of the mucous membrane, skin or the body. Tell your healthcare provider right away if you get fever, severe cough with or without an increase in mucus (sputum) production, severe sore throat, shortness of breath, burning or pain when urinating, unusual vaginal discharge or irritation, redness, swelling or pain in any part of the body.
- **severe bleeding.** STIVARGA can cause bleeding, which can be serious and sometimes lead to death. Tell your healthcare provider if you have any signs of bleeding while taking STIVARGA, including: vomiting blood or if your vomit looks like coffee grounds, pink or brown urine, red or black (looks like tar) stools, coughing up blood or blood clots, menstrual bleeding that is heavier than normal, unusual vaginal bleeding, nose bleeds that happen often, bruising, and lightheadedness.
- **a tear in your stomach or intestinal wall (bowel perforation).** STIVARGA may cause a tear in your stomach or intestinal wall (bowel perforation) that can be serious and sometimes lead to death. Tell your healthcare provider right away if you get severe pains or swelling in your stomach area (abdomen), fever, chills, nausea, vomiting, or dehydration.
- **a skin problem called hand-foot skin reaction and severe skin rash.** Hand-foot skin reactions are common and sometimes can be severe. Tell your healthcare provider right away if you get redness, pain, blisters, bleeding, or swelling on the palms of your hands and soles of your feet, or a severe rash.
- **high blood pressure.** Your blood pressure should be checked every week for the first 6 weeks of starting STIVARGA. Your blood pressure should be checked regularly and any high blood pressure should be treated while you are receiving STIVARGA. Tell your healthcare provider if you have severe headaches, light-headedness, or changes in your vision.
- **decreased blood flow to the heart and heart attack.** Get emergency help right away if you get symptoms such as chest pain, shortness of breath, feel dizzy, or feel like passing out.
- **a condition called Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** Call your healthcare provider right away if you get severe headaches, seizure, confusion, change in vision, or problems thinking.
- **risk of wound healing problems.** Wounds may not heal properly during STIVARGA treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with STIVARGA.
 - You should stop taking STIVARGA at least 2 weeks before planned surgery.
 - Your healthcare provider should tell you when you may start taking STIVARGA again after surgery.

The most common side effects with STIVARGA include pain including stomach-area (abdomen); tiredness, weakness, fatigue; diarrhea (frequent or loose bowel movements); decreased appetite; infection; voice change or hoarseness; increase in certain liver function tests; fever; swelling, pain, and redness of the lining in your mouth, throat, stomach, and bowel (mucositis); and weight loss.

Call your healthcare provider for medical advice about side effects. You are encouraged to report side effects or quality complaints of products to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.



Access Services by Bayer™ can connect eligible STIVARGA patients to available affordability support options. Call 1-800-288-8374 to learn more.

For patients with commercial health insurance:

\$0 CO-PAY FOR ELIGIBLE PATIENTS*

- Up to the program maximum. Benefit limitations apply
- Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible
- Full terms and conditions apply*

3 WAYS TO ENROLL IN \$0 CO-PAY

1. Directly via www.zerocopaysupport.com
2. Via phone 1-647-245-5622
3. Contact the SPP Network



Bayer US Patient Assistance Foundation

The Bayer US Patient Assistance Foundation is a charitable organization that helps eligible patients get their Bayer prescription medicine at no cost. Please contact the program at 1-866-2BUSPAF (228-7723) Monday-Friday, 9:00 AM-6:00 PM EST, or visit the foundation website at www.patientassistance.bayer.us to see if you might qualify for assistance.

*PROGRAM DETAILS:

Patients are eligible if they are commercially insured and may pay as little as \$0 per month up to the program maximum. Benefit limitations apply. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. Full terms and conditions apply, see www.zerocopaysupport.com.

PATIENT INSTRUCTIONS:

After enrolling in the program, present this card and your insurance card along with a valid prescription at any participating pharmacy. By using this offer, you are certifying that you understand and agree to comply with the program restrictions section below. Patients with questions about the Stivarga Co-Pay Savings Program should call 1-647-245-5622.

RESTRICTIONS:

This offer is valid in the United States. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, Tricare, or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. By using this offer, the patient is certifying that they will comply with any terms of their health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. Offer not valid for patients under 18 years of age. This program is not insurance. It is illegal to (or offer to) sell, purchase, or trade this offer. This offer is not transferable and is limited to one offer per person. Not valid if reproduced. Void where prohibited by law. Program managed by ConnectiveRx on behalf of Bayer Pharmaceuticals. Bayer reserves the right to rescind, revoke or amend this offer without notice at any time.

PHARMACIST INSTRUCTIONS:

Submit the claim to the primary Third Party Payer first, then submit the balance due to SS&C as a Secondary Payer COB [coordination of benefits] with patient responsibility amount and a valid Other Coverage Code (eg, 8). Patients are eligible if they are commercially insured and may pay as little as \$0 per month up to the program maximum. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible.

Please see Important Safety Information on pages 1 and 3 and click for full [Prescribing Information](#), including the Boxed Warning.

WWW.STIVARGA-US.COM

