Patient Information
STIVARGA (sti-VAR-gah)
(regorafenib)
tablets

What is the most important information I should know about STIVARGA?

STIVARGA can cause serious side effects, including:

Liver problems. STIVARGA can cause liver problems which can be serious and 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. Tell your healthcare provider right away if you get any of these symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes (jaundice)
- nausea or vomiting
- dark "tea-colored" urine
- change in sleep pattern

What is STIVARGA?

STIVARGA is a prescription medicine used to treat people 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 tumors) 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.

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. See **"What are the possible side effects of STIVARGA?"**
- 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 breastfeeding or plan to breastfeed. 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 medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. STIVARGA may affect the way other medicines work, and other medicines may affect how STIVARGA works.

How should I take STIVARGA?

- Take STIVARGA exactly as your healthcare provider tells you.
- You will usually take STIVARGA 1 time a day for 21 days (3 weeks) and then stop for 7 days (1 week). This is 1 cycle of treatment. Repeat this cycle for as long as your healthcare provider tells you to.
- Swallow STIVARGA tablets whole with water following a low-fat meal.
- Take STIVARGA at the same time each day following a low-fat meal that contains less than 600 calories and less than 30% fat.
- If you miss a dose, 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 take too much STIVARGA call your healthcare provider or go to the nearest emergency room right away.

What should I avoid while taking STIVARGA?

- Avoid drinking grapefruit juice and taking St. John's Wort during treatment with STIVARGA. These can affect the way STIVARGA works.

What are the possible side effects of STIVARGA?

STIVARGA can cause serious side effects including:

- See "**What is the most important information I should know about STIVARGA?**"
- **Infection.** STIVARGA may lead to a higher risk of infections especially of the urinary tract, nose, throat and lung. STIVARGA may also 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 during treatment with 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
  - 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 pain in your stomach-area (abdomen)
  - swelling of the abdomen
  - fever
  - chills
  - nausea
  - vomiting
  - 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 or 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 during treatment with STIVARGA. Tell your healthcare provider if you have severe headaches, lightheadedness, 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 of STIVARGA include:

- pain, including stomach-area (abdomen)
- tiredness, weakness, fatigue
- frequent or loose bowel movements (diarrhea)
- decreased appetite
- infection
- voice changes or hoarseness
- increase in certain liver function test
- fever
- swelling, pain and redness of the lining in your mouth, throat, stomach and bowel (mucositis)
- weight loss

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with STIVARGA if you have certain side effects.

These are not all of the possible side effects of STIVARGA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store STIVARGA?

- Store STIVARGA tablets at room temperature between 68° F to 77° F (20° C to 25°C).
- Keep STIVARGA in the bottle that it comes in. Do not put STIVARGA tablets in a daily or weekly pill box.
- The STIVARGA bottle contains a desiccant to help keep your medicine dry. Keep the desiccant in the bottle.
- Keep the bottle of STIVARGA tightly closed.
- Safely throw away (discard) any unused STIVARGA tablets after 7 weeks of opening the bottle.

Keep STIVARGA and all medicines out of the reach of children.

General information about the safe and effective use of STIVARGA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use STIVARGA for a condition for which it was not prescribed. Do not give STIVARGA to other people even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about STIVARGA that is written for health professionals.

What are the ingredients in STIVARGA?

Active ingredient: regorafenib

Inactive ingredients: cellulose microcrystalline, croscarmellose sodium, magnesium stearate, povidone and colloidal silicon dioxide.

Film coat: ferric oxide red, ferric oxide yellow, lecithin (soy), polyethylene glycol 3350, polyvinyl alcohol, talc and titanium dioxide.

Manufactured for Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 07981 USA.
For more information, go to www.STIVARGA-US.com or call 1-888-842-2937.

This Patient Information has been approved by the U.S. Food and Drug Administration.
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