

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

Read this Patient Information before you start taking Stivarga and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

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

Stivarga has not been used to treat children less than 18 years of age.

What should I tell my healthcare provider before taking Stivarga?

Before you take Stivarga, tell your healthcare provider if you:

- have liver problems
- have bleeding problems
- have high blood pressure
- have heart problems or chest pain
- plan to have any surgical procedures
- have any other medical conditions
- are pregnant or plan to become pregnant. Stivarga can harm your unborn baby. Females and males should use effective birth control during treatment with Stivarga and for 2 months after your last dose of Stivarga. Tell your healthcare provider right away if you or your partner becomes pregnant either while taking Stivarga or within 2 months after your last dose of Stivarga.
- are breastfeeding or plan to breastfeed. It is not known if Stivarga passes into your breast milk. You and your healthcare provider should decide if you will take Stivarga or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Stivarga may affect the way other medicines work, and other medicines may affect how Stivarga works.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

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.
- Take Stivarga at the same time each day with a low-fat breakfast.
Examples of a low-fat breakfast include:
 - 2 slices of white toast with 1 tablespoon of low-fat margarine and 1 tablespoon of jelly, and 8 ounces of skim milk (319 calories and 8.2 grams fat), **or**
 - 1 cup of cereal, 8 ounces of skim milk, 1 slice of toast with jelly, apple juice, and 1 cup of coffee or tea (520 calories and 2 grams fat).
- Your healthcare provider may stop your treatment or change the dose of your treatment if you get side effects.
- 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 while taking 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?**"
- **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
- **a skin problem called hand-foot skin reaction and severe skin rash.** Hand-foot skin reactions can cause redness, pain, blisters, bleeding, or swelling on the palms of your hands or soles of your feet. If you get this side effect or a severe skin rash, your healthcare provider may stop your treatment for some time.
- **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, lightheadedness, or changes in your vision.

- **decreased blood flow to the heart and heart attack.** Get emergency help right away and call your healthcare provider 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.
- **a tear in your stomach or intestinal wall (bowel perforation).** Stivarga may cause a tear in your stomach or 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
 - high fever
- **wound healing problems.** If you need to have a surgical procedure, tell your healthcare provider that you are taking Stivarga. You should stop taking Stivarga at least 2 weeks before any planned surgery.

The most common side effects of Stivarga include:

- tiredness, weakness, fatigue
- frequent or loose bowel movements (diarrhea)
- loss of appetite
- swelling, pain and redness of the lining in your mouth, throat, stomach and bowel (mucositis)
- voice changes or hoarseness
- infection
- pain in other parts of your body
- weight loss
- nausea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Stivarga. For more information, ask your healthcare provider or pharmacist.

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 28 days of opening the bottle.

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

General information about 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.

This leaflet summarizes the most important information about Stivarga. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Stivarga this is written for health professionals.

For more information, go to www.STIVARGA-US.com or call 1-888-842-2937.

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.

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