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Regorafenib

# Regorafenib 🖘

**Generic name:** regorafenib [ RE-goe-RAF-e-nib ]

Brand name: Stivarga

Dosage form: oral tablet (40 mg)

Drug classes: Multikinase inhibitors, VEGF/VEGFR inhibitors



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Uses Side effects Warnings Before taking Dosage Interactions

## What is regorafenib?

Regorafenib is used to treat colorectal cancer and liver cancer. It is also used to treat a rare type of tumor that can affect the esophagus, stomach, or intestines.

Regorafenib is usually given after other cancer medications have been tried without success.

Regorafenib may also be used for purposes not listed in this medication guide.

## Regorafenib side effects

Get emergency medical help if you have **signs of an allergic reaction** (hives, difficult breathing, swelling in your face or throat) **or a severe skin reaction** (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Regorafenib can cause serious or life-threatening liver problems. Call your doctor at once if you have nausea, vomiting, sleep problems, dark urine, or jaundice (yellowing of the skin or eyes).

Also call your doctor at once if you have:

- headache, confusion, change in mental status;
- · vision changes;
- · a seizure:
- pain, blisters, bleeding, or severe rash in the palms of your hands or the soles of your feet;
- heart problems--chest pain, shortness of breath, feeling like you might pass out;
- increased blood pressure--severe headache, blurred vision, pounding in your neck or ears;
- perforation (a hole or tear) in your stomach or intestines--fever, chills, severe stomach pain or swelling, nausea, vomiting, increased thirst, decreased urination;

- **severe bleeding**--bruising, nosebleeds, heavy menstrual periods or abnormal vaginal bleeding, blood in your urine, bloody or tarry stools, coughing up blood, or any bleeding that will not stop; or
- signs of infection--fever, sore throat, feeling short of breath, cough with or without mucus, vaginal itching or discharge, pain or burning when you urinate, or redness and swelling anywhere in your body.

Your cancer treatments may be delayed or permanently discontinued if you have certain side effects.

#### Common side effects of regorafenib may include:

- · diarrhea, nausea, stomach pain;
- · loss of appetite, weight loss;
- · increased blood pressure;
- · fever, infection;
- · abnormal liver function tests;
- pain or redness in your mouth or throat, hoarse voice; or
- · feeling weak or tired.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Regorafenib side effects (more detail)

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# **Warnings**

Use birth control to prevent pregnancy, whether you are a man or a woman. Avoid pregnancy for at least 2 months after you stop using regorafenib.

Regorafenib can cause serious or life-threatening liver problems. Call your doctor at once if you have nausea, vomiting, sleep problems, dark urine, or jaundice (yellowing of the skin or eyes).

# Before taking this medicine

Tell your doctor if you have ever had:

- liver disease;
- high blood pressure;
- a bleeding or blood clotting disorder;
- · heart disease, chest pain; or

• if you recently had surgery or plan to have surgery.

Both men and women using this medicine should use effective birth control to prevent pregnancy. Regorafenib can harm an unborn baby if the mother or father is using this medicine.

Keep using birth control for at least 2 months after your last dose. Tell your doctor right away if a pregnancy occurs while either the mother or the father is using regorafenib.

Do not breastfeed while using this medicine, and for at least 2 weeks after your last dose.

## How should I take regorafenib?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

Regorafenib is usually taken daily for 3 weeks followed by 1 week off the medicine. Your doctor will determine how many times you should repeat this treatment cycle.

Regorafenib works best if you take it after a low-fat, low-calorie meal. Swallow the tablet whole with a full glass of water.

Take the medicine at the same time each day.

Your blood pressure will need to be checked often. Your liver function will also need to be checked.

If you need surgery, tell your surgeon you currently use regorafenib. Regorafenib can cause problems with wounds healing, including surgical incisions. You should stop taking this medicine at least 2 weeks before you have surgery. Carefully follow your doctor's instructions about when to stop and start taking regorafenib.

Store at room temperature away from moisture and heat. Keep the tablets in their original container, along with the packet or canister of moisture-absorbing preservative. **Do not put regorafenib tablets into a daily pill box.** 

Throw away any regorafenib tablets not used within 7 weeks after opening the bottle.

## Regorafenib dosing information

#### **Usual Adult Dose for Colorectal Cancer:**

160 mg orally once a day for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity

### Uses:

- -Metastatic colorectal cancer (CRC) previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and an anti-EGFR therapy if RAS wild-type
- -Locally advanced, unresectable or metastatic GI stromal tumor (GIST) previously treated with imatinib mesylate and sunitinib malate
- -Hepatocellular carcinoma (HCC) previously treated with sorafenib

#### **Usual Adult Dose for Gastrointestinal Stromal Tumor:**

160 mg orally once a day for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity

Uses:

- -Metastatic colorectal cancer (CRC) previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and an anti-EGFR therapy if RAS wild-type
- -Locally advanced, unresectable or metastatic GI stromal tumor (GIST) previously treated with imatinib mesylate and sunitinib malate
- -Hepatocellular carcinoma (HCC) previously treated with sorafenib

### **Usual Adult Dose for Hepatocellular Carcinoma:**

160 mg orally once a day for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity

#### Uses:

- -Metastatic colorectal cancer (CRC) previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and an anti-EGFR therapy if RAS wild-type
- -Locally advanced, unresectable or metastatic GI stromal tumor (GIST) previously treated with imatinib mesylate and sunitinib malate
- -Hepatocellular carcinoma (HCC) previously treated with sorafenib
- <u>Detailed Regorafenib dosage information</u>

## What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. **Do not** take two doses at one time.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid while taking regorafenib?

Grapefruit and grapefruit juice may interact with regorafenib and lead to potentially dangerous effects. Avoid the use of grapefruit products while taking regorafenib.

Avoid taking an herbal supplement containing St. John's wort.

## What other drugs will affect regorafenib?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Many drugs can affect regorafenib. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed here. Tell your doctor about all your current medicines and any medicine you start or stop using.

Regorafenib drug interactions (more detail)

## Does regorafenib interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

| regorafenib       |     |
|-------------------|-----|
| +                 |     |
| Enter a drug name | Add |

### More about regorafenib

- · Check interactions
- · Compare alternatives
- Reviews (14)
- Side effects
- Dosage information
- During pregnancy
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### **Patient resources**

· Regorafenib advanced reading

### Other brands

Stivarga

### **Professional resources**

• Regorafenib monograph

### Other brands

Stivarga

## Related treatment guides

- Gastrointestinal Stromal Tumor
- Colorectal Cancer
- Hepatocellular Carcinoma

### **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

#### Medical Disclaimer

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#### **DRUG STATUS**

**Availability** 

Rx Prescription only

**Pregnancy & Lactation** 

& Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

Drug history at FDA

### **User Reviews & Ratings**

4.4 / 10

14 Reviews

### **Images**

Stivarga (regorafenib) 40 mg (BAYER 40)

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