Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

Regorafenib

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Stivarga

Brand Names: Canada

Stivarga

Warning

- Severe and sometimes deadly liver problems have happened with this drug. Call your doctor right away if you have signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Have your blood work and other lab tests checked as you have been told by your doctor.

What is this drug used for?

- It is used to treat cancer.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: High blood pressure or liver disease.
- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, seizures, and others. There are many drugs that must not be taken with this drug.
- If you are breast-feeding. Do not breast-feed while you take this drug and for 2 weeks after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid grapefruit and grapefruit juice.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- You may have more of a chance of getting an infection. Some infections have been severe or deadly. Wash hands often. Stay away from people with infections, colds, or flu.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor. Rarely, some bleeding problems have been deadly.
- Very bad and sometimes deadly holes in the GI (gastrointestinal) tract or fistulas have happened with this drug. Talk with the doctor.
- This drug may affect how wounds heal. If you need to have surgery, you may need to stop this drug before surgery. Start taking it again after surgery as you have been told by your doctor. Call your doctor right away if

you have a wound that does not heal or any other wound problems.

- If you are of Asian descent, use this drug with care. You could have more side effects.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you plan to get pregnant or father a child, talk with your doctor before taking this drug.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- If you or your sex partner may become pregnant, use birth control while taking this drug and for 2 months after the last dose. If you or your sex partner gets pregnant, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red,

swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, fast or abnormal heartbeat, severe dizziness or passing out, increased thirst, seizures, feeling very tired or weak, decreased appetite, unable to pass urine or change in the amount of urine produced, dry mouth, dry eyes, or severe upset stomach or throwing up.

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of low thyroid levels like constipation; not able to handle cold; memory problems; mood changes; or a burning, numbness, or tingling feeling that is not normal.
- Redness or irritation of the palms of hands or soles of feet.
- Stomach swelling or severe stomach pain.
- New or unusual vaginal discharge or odor.
- Feeling very sleepy.
- Shakiness.
- The chance of decreased blood flow to the heart and heart attack may be raised with this drug. Call your doctor right away if you have chest pain, dizziness, shortness of breath, or feel like passing out.
- A very bad and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with this drug. Call your doctor right away if you have signs like feeling confused, lowered alertness, change in eyesight, loss of eyesight, seizures, or very bad headache.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It

can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Hair loss.
- Feeling tired or weak.
- Headache.
- Weight loss.
- Mouth or throat pain or irritation.
- Change in voice.
- Stomach pain.
- Muscle spasm.
- Diarrhea, throwing up, upset stomach, and decreased appetite are common with this drug. If these happen, talk with your doctor about ways to lower these side effects. Call your doctor right away if any of these effects bother you, do not get better, or are severe.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take this drug by mouth with water after a low-fat meal. The low-fat meal must be less than 600 calories and less than 30% fat.
- Take this drug at the same time of day.
- Swallow whole. Do not chew, break, or crush.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it on the same day you missed the dose.
- If you do not think about the missed dose until the next day, skip the missed dose and go back to your normal time.

- Do not take 2 doses on the same day.

How do I store and/or throw out this drug?

- Store tablets in the original container at room temperature. Keep the cap tightly closed. Do not take out the antimoisture cube or packet.
- Throw away any part not used 7 weeks after opening the bottle.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please

talk with your doctor, nurse, pharmacist, or other health care provider.

- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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