

# Medical Oncology

## Drug Information Sheet

**Regorafenib (Stivarga):** a drug to treat your cancer.

### What should I avoid while receiving *Regorafenib (Stivarga)*?

- Do not eat grapefruit or drink grapefruit juice while taking *Regorafenib (Stivarga)*.
- Do not take St. John's Wort with this drug.

### Dose and Schedule:

- You will take this medicine by mouth.
- *Regorafenib (Stivarga)* should be taken at the same time every day (morning or evening).
- *Regorafenib (Stivarga)* should be taken with water after a low-fat meal that contains less than 600 calories and less than 30% fat (see Low-Fat Meals Information Sheet).
- Your dose may vary, but the usual dose of *Regorafenib (Stivarga)* should be taken once daily for 21 days followed by 7 days off-treatment. The dose may be adjusted by your care provider based on your individual needs.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Swallow the tablets whole with water. Do not crush, open, break, chew or dissolve the medicine in water.
- If you have any unused *Regorafenib (Stivarga)*, do not throw it in the trash and do not flush it down the sink or toilet. Talk to your doctor or pharmacist about proper disposal of *Regorafenib (Stivarga)*.
- *Regorafenib (Stivarga)* has many drug interactions. Tell your doctor all the prescription medicines, over-the-counter medicines, vitamins, and herbal products you are taking.
- Your doctor may change your dose, briefly stop or completely stop treatment with *Regorafenib (Stivarga)* if you have side effects.
- **DO NOT START A NEW CYCLE WITHOUT TALKING TO YOUR DOCTOR FIRST.**

If you miss a dose of *Regorafenib (Stivarga)*:

- Skip the missed dose and return to normal schedule the following day.
- Do not take an extra dose or two doses at one time.
- If vomiting occurs after taking a dose, take the next dose at the scheduled time.
- Write down if you miss a dose and let your doctor know about any missed doses.

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Storage and Handling:	
<ul style="list-style-type: none"> <li>• You will get this drug from a special pharmacy through the mail. We will help you through the process.</li> <li>• The drug must be kept in a secure place out of reach of children and pets, so no one else can take this drug. Never share <i>Regorafenib (Stivarga)</i> with anyone else.</li> <li>• Store <i>Regorafenib (Stivarga)</i> at room temperature in a dry place and away from light. Do not store in a bathroom.</li> <li>• Keep in original bottle: do NOT place tablets in a pill box.</li> </ul>	
<ul style="list-style-type: none"> <li>• Whenever possible, give <i>Regorafenib (Stivarga)</i> to yourself and follow the steps below. If a family member, friend or caregiver gives <i>Regorafenib (Stivarga)</i> to you, they also need to follow these steps               <ul style="list-style-type: none"> <li>○ Wash hands with soap and water</li> <li>○ Put on gloves to avoid touching the medicine (gloves are not needed if you give <i>Regorafenib (Stivarga)</i> to yourself).</li> <li>○ Do not let women who are pregnant or who may get pregnant touch the tablets without wearing gloves.</li> <li>○ Carefully remove <i>Regorafenib (Stivarga)</i> from its package to a small disposable cup.</li> <li>○ Do not lay the medicine on the counter.</li> <li>○ Take the medicine immediately by mouth with water.</li> <li>○ Remove gloves and do not use them for anything else.</li> <li>○ Throw gloves and disposable cup in household trash.</li> <li>○ Wash hands with soap and water.</li> <li>○ Do not touch or handle crushed or broken tablets.</li> </ul> </li> </ul>	

You **MAY OR MAY NOT** experience the side effects listed below

Possible Side Effects:	What to do:
<b>Increased risk for infection due to decreased blood counts</b>	<ul style="list-style-type: none"> <li>• Avoid contact with people who have infections, colds or flu.</li> <li>• Wash your hands often.</li> <li>• Report chills or a fever of 100.4° or higher to your doctor right away, day or night.</li> <li>• Report any signs or symptoms of infection, such as cough, burning with urination, skin redness or sores.</li> <li>• Call your doctor before taking any medicine for a fever or chills.</li> </ul>
<b>Lower than normal red blood cells</b> Anemia	Call you doctor if you have: <ul style="list-style-type: none"> <li>○ shortness of breath with activity</li> <li>○ fatigue</li> <li>○ dizziness</li> <li>○ fast heartbeat or a heartbeat that does not feel normal</li> <li>○ headache</li> </ul>

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Possible Side Effects:	What to do:
<p><b>Increased risk for bleeding due to decreased blood counts</b></p>	<ul style="list-style-type: none"> <li>• Report signs of bleeding or bruising.</li> <li>• Avoid taking aspirin or aspirin products unless your doctor tells you to take it.</li> <li>• Use soft toothbrush.</li> <li>• Use electric razor.</li> <li>• Talk to your doctor before any scheduled medical or dental procedures.</li> <li>• Call your doctor if you have:               <ul style="list-style-type: none"> <li>○ Severe headache.</li> <li>○ Blood in stools or urine.</li> <li>○ Bleeding for a long period.</li> <li>○ Uncontrolled bleeding</li> <li>○ Bruising</li> </ul> </li> </ul>
<p><b>Liver problems</b></p>	<ul style="list-style-type: none"> <li>• Lab results will be monitored.</li> <li>• Call your doctor if you have:               <ul style="list-style-type: none"> <li>○ dark urine (tea colored)</li> <li>○ severe right sided stomach pain</li> <li>○ light colored stools</li> <li>○ bruising or if you start to bleed easily</li> <li>○ yellowing of skin or eyes</li> <li>○ severe nausea or throwing up</li> <li>○ unexplained weight gain</li> <li>○ your belly feels big or bloated</li> </ul> </li> </ul>
<p><b>Hand and Foot Syndrome</b> tenderness and redness of palms and bottom of feet where skin becomes dry and peels.</p>	<ul style="list-style-type: none"> <li>• Apply moisturizing lotion often.</li> <li>• Avoid using hot water or standing for long times.</li> <li>• Wear gloves and comfortable shoes to prevent injuries.</li> <li>• Call your doctor if you have:               <ul style="list-style-type: none"> <li>○ redness, swelling, peeling, or tenderness of hands or feet</li> <li>○ any skin redness, itching, rash or blisters that ooze or peel</li> <li>○ tingling/burning or your skin is sensitive to touch</li> <li>○ a hard time walking or using your hands</li> </ul> </li> </ul>
<p><b>Bone, muscle, joint pain</b></p>	<p>Use pain prescription as directed. Notify your doctor if the pain is uncontrolled.</p>
<p><b>Diarrhea</b></p>	<ul style="list-style-type: none"> <li>• Keep well hydrated with water or fluids.</li> <li>• Take over the counter anti-diarrhea medicine (Immodium A-D™ or loperamide HCL). Use the “<i>Helpful Tips for Diarrhea after Chemotherapy or Radiation Therapy</i>” instruction sheet.</li> <li>• Call your doctor if you have:               <ul style="list-style-type: none"> <li>○ More than 4 loose stools in 24 hours</li> <li>○ A fever of 100.4° or higher</li> <li>○ bad stomach pain or cramps</li> <li>○ dizziness or feel faint</li> <li>○ bloody stools (dark, tarry or sticky)</li> </ul> </li> </ul>

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<b>Possible Side Effects:</b>	<b>What to do:</b>
<b>Severe skin and mouth reactions</b>	<ul style="list-style-type: none"> <li>• Use a moisturizing cream free from alcohol, perfume or dye at least twice a day.</li> <li>• When outside, use sunscreen and wear clothing and eyewear that protects you from the sun</li> <li>• Choose mild soaps.</li> <li>• Use tepid water, rather than hot water.</li> <li>• Wear loose-fitting cotton clothing</li> <li>• Apply cool, wet cloth to soothe skin</li> <li>• Avoid using perfumes and cologne.</li> <li>• Avoid rubbing and scratching</li> <li>• Call your doctor if you have:               <ul style="list-style-type: none"> <li>○ A skin rash</li> <li>○ Red, swollen, blistered, or peeling skin</li> <li>○ Red or irritated eyes</li> <li>○ Sores in your mouth, throat, nose or eyes</li> </ul> </li> <li>• Your doctor may prescribe anti-inflammation creams or medicine by mouth.</li> <li>• Patient Starter kit is available.</li> </ul>
<b>High Blood Pressure</b>	<ul style="list-style-type: none"> <li>• Let your primary care doctor know that you are taking <i>Regorafenib (Stivarga)</i>.</li> <li>• Your blood pressure will be checked.               <ul style="list-style-type: none"> <li>○ Once a week for first 6 weeks</li> <li>○ With each visit</li> </ul> </li> <li>• Contact your doctor if you have:               <ul style="list-style-type: none"> <li>○ headaches</li> <li>○ shortness of breath</li> <li>○ nosebleeds</li> <li>○ dizziness or passing out</li> <li>○ change in eyesight</li> </ul> </li> </ul>
<b>Nausea/vomiting Decreased appetite</b>	<ul style="list-style-type: none"> <li>• Take nausea medicine as instructed. Let your doctor know if it is not working for you.</li> <li>• Eat smaller, frequent meals.</li> <li>• Try liquid nutrition supplements (Boost, Ensure).</li> <li>• A dietitian is available to talk with you.</li> </ul>
<b>Protein in urine.</b>	<ul style="list-style-type: none"> <li>• Lab tests will be done to check your urine.</li> </ul>
<b>Fatigue or weakness</b>	<ul style="list-style-type: none"> <li>• You may be more tired than usual or have less energy.</li> <li>• Stay as active as possible, but know it is okay to rest as needed.</li> <li>• Try to do some activity every day.</li> <li>• Plan your activities, and do them at a time of day when you feel more energetic.</li> <li>• Avoid driving or doing other tasks that call for you to be alert.</li> </ul>

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<b>Possible Side Effects:</b>	<b>What to do:</b>
<p><b>Changes in electrolytes and other lab values</b>            Low calcium levels            Low potassium levels            Low sodium levels            Low phosphorus level</p>	<ul style="list-style-type: none"> <li>• Your lab values will be checked.</li> <li>• The strength and solidness of your bones will be tested (bone density test).</li> <li>• Take calcium (at least 500 mg) and Vitamin D (400 IU) daily.</li> <li>• Call you doctor if you are feeling confused</li> <li>• Notify your doctor if you have symptoms of low blood calcium:               <ul style="list-style-type: none"> <li>○ spasms, twitches or cramps of your muscles</li> <li>○ numbness or tingling in your fingers, toes or around your mouth</li> </ul> </li> <li>• Call your doctor if you have symptoms of low phosphorus               <ul style="list-style-type: none"> <li>○ changes in eyesight</li> <li>○ mood changes</li> <li>○ muscle pain or weakness</li> <li>○ shortness of breath or other breathing problems</li> <li>○ trouble swallowing</li> </ul> </li> <li>• Call your doctor if you have signs of low potassium:               <ul style="list-style-type: none"> <li>○ weakness</li> <li>○ fatigue</li> <li>○ muscle cramps or twitching</li> <li>○ constipation</li> <li>○ heart beat that does not feel normal</li> </ul> </li> <li>• Call your doctor if you have signs of low blood sodium:               <ul style="list-style-type: none"> <li>○ headache</li> <li>○ trouble focusing</li> <li>○ problems with your memory</li> <li>○ change in balance</li> <li>○ weakness</li> </ul> </li> </ul>
<p><b>Regorafenib (Stivarga) will be in urine and stool for 48 hours.</b></p>	<ul style="list-style-type: none"> <li>• Caregivers will need to handle soiled linens and clothing wearing gloves or using a bag as a barrier.</li> <li>• Keep your soiled items separate from others' dirty laundry and wash right away.</li> <li>• Women who are pregnant should not handle your soiled clothing or linens.</li> <li>• Wash any skin that body waste has touched with soap and water.</li> <li>• You may use the same toilet that you normally use.</li> <li>• If the toilet or toilet seat becomes dirty with urine, stool or vomit, clean the surfaces before other people use the toilet</li> <li>• Wash hands with soap and water after using the toilet.</li> <li>• <b>It is safe to hug and kiss.</b></li> </ul>

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Possible Side Effects:	What to do:
<b>Avoid pregnancy</b>	<ul style="list-style-type: none"> <li>• Women should not become pregnant and men should not get a partner pregnant while taking <i>Regorafenib (Stivarga)</i>.</li> <li>• This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.</li> <li>• Use birth control that you can trust to prevent pregnancy while taking this drug and for <b>2 months</b> after stopping this drug.</li> <li>• If you or your sex partner gets pregnant while taking this drug or within <b>2 months</b> after stopping this drug, call your doctor right away.</li> <li>• May cause fertility problems.</li> </ul>

### Less common side effects that may happen

Less common side effects	What to do:
<b>Serious allergic reactions</b> Up to 24 hours after infusion	<ul style="list-style-type: none"> <li>• Call 911 and go to the Emergency Department right away if you have any symptoms:               <ul style="list-style-type: none"> <li>○ trouble breathing</li> <li>○ chest tightness</li> <li>○ swelling of your face, lips, or tongue</li> </ul> </li> <li>• Call you doctor if you develop:               <ul style="list-style-type: none"> <li>○ a rash</li> <li>○ itching</li> <li>○ hives</li> <li>○ fever</li> <li>○ chills</li> <li>○ pain in the abdomen or back</li> <li>○ cough</li> <li>○ runny or stuffy nose</li> </ul> </li> </ul>
<b><i>Regorafenib (Stivarga)</i> may increase risk of heart attack</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you have a history of coronary artery disease, heart failure, or an abnormal heart rhythm</li> <li>• Call 911 right away if you have any of these symptoms:               <ul style="list-style-type: none"> <li>○ Chest pain or chest discomfort/tightness that may spread to your neck, jaw or back.</li> <li>○ Cold sweat</li> <li>○ Shortness of breath or trouble breathing</li> <li>○ Severe dizziness and fainting.</li> </ul> </li> </ul>

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Less common side effects	What to do:
<b>Bleeding problems</b>	<ul style="list-style-type: none"> <li>• Call your doctor if you have signs of bleeding:               <ul style="list-style-type: none"> <li>○ bad headache, dizziness or weakness</li> <li>○ coughing up blood or blood clots</li> <li>○ vomiting blood or your vomit looks like coffee grounds</li> <li>○ red or black stools that look like tar or are sticky</li> <li>○ menstrual bleeding that is heavier than normal</li> <li>○ unusual or heavy bleeding that you cannot stop</li> </ul> </li> </ul>
<b>PRES/RPLS</b> Rare swelling in the back part of the brain	Call your doctor if you have: <ul style="list-style-type: none"> <li>○ loss of eyesight</li> <li>○ confusion</li> <li>○ headache</li> <li>○ lethargy</li> <li>○ seizure</li> <li>○ visual or neurologic disturbances</li> </ul>
<b>Wounds that do not heal</b>	<ul style="list-style-type: none"> <li>• <i>Regorafenib (Stivarga)</i> should be stopped for at least 14 days prior to any surgery procedure.</li> <li>• <i>Regorafenib (Stivarga)</i> should not be taken for at least 14 days following any surgery or until your wound begins to heal.</li> </ul>
<b>Coumadin (Warfarin) dosing</b>	<ul style="list-style-type: none"> <li>• If you are taking Coumadin (warfarin), talk with your doctor. You may need to have your blood work checked more closely while you are taking it with this medicine.</li> <li>• Increased risk of bleeding when taking <i>Coumadin (warfarin)</i> and <i>Regorafenib (Stivarga)</i>.</li> </ul>
<b>These are not all of the side effects that may occur. If you have questions about side effects, call your doctor.</b>	