

## Sorafenib

Your treatment is called sorafenib (sore-AH-fen-ib) or Nexavar® (NEX-a-var). It is commonly used to treat advanced renal cell carcinoma and has also been used to treat other diseases. Sorafenib is a new type of drug that targets cancer cells more precisely than chemotherapy drugs. It works by blocking tumor cells from growing and by stopping new blood vessels (which bring nutrients and oxygen to the tumor to help it grow) from forming.

### What Do I Need to Know Before Starting Treatment?

Be sure to tell your healthcare provider about any prescription or over-the-counter products you are taking, including dietary supplements, vitamins, herbal medicines and homeopathic remedies.

Use an effective birth control method while you are being treated. Sorafenib can cause harm to a fetus, so be sure to tell your healthcare provider right away if you or your partner become pregnant.

Avoid breastfeeding during treatment. It is not known if sorafenib passes into breast milk.

Some drugs can cause sterility. Talk with your healthcare provider about your options if you want to have children in the future.

Do not get any immunizations or vaccinations while you are being treated without the approval of your healthcare provider.

### What Do I Need to Know Before Starting Sorafenib?

Sorafenib commonly causes a rash and a skin problem called hand-foot syndrome (HFS). Please see "What Are the Possible Side Effects" in the chart below. HFS can cause redness, pain, swelling or blisters on the palms of your hands or soles of your feet. These symptoms are generally mild and appear during the first six weeks of treatment. If you have skin problems, your healthcare provider may adjust your dose of sorafenib or stop your treatment for a while.

Sorafenib may cause a severe increase in blood pressure. Your healthcare provider will check your blood pressure regularly and may give you medicine to treat high blood pressure. Tell your healthcare provider if you are already being treated for high blood pressure.

In rare cases, sorafenib can cause bowel perforation (holes in the stomach, intestines or colon) that must be repaired through surgery. Call your healthcare provider right away if you have abdominal pain with nausea, vomiting, blood in your stool, constipation or fever.

Sorafenib can increase your chance of bleeding. In rare cases, the bleeding can be severe. This side effect is more common in patients taking warfarin (Coumadin®). Tell your healthcare provider if you start having nosebleeds, bleeding from your gums or blood in your urine or stool.

In rare cases, sorafenib can cause a heart attack or heart failure. This side effect may be more common in patients with a history of heart disease. Tell your healthcare provider if you have a history of heart disease or if you have anxiety, cold sweats, pain in the chest, increased heart rate or pain in the neck, jaw or arms. Your healthcare provider may decide to stop your treatment with sorafenib if you develop heart problems.

Sorafenib can cause slow or incomplete wound healing. Tell your healthcare provider if you have wounds that do not heal. If you are having surgery, your healthcare provider may suggest that you stop taking sorafenib.

Your treatment can interact with other substances, including:

- Warfarin (Coumadin®)
- Anti-seizure medications, such as phenytoin (Dilantin®), carbamazepine (Tegretol®) and phenobarbital
- Dexamethasone
- St. John's wort
- Rifampin

- Irinotecan
- Doxorubicin

Please note this list is a summary and does not contain all possible drug interactions. Contact your healthcare provider if you are taking any medications that can interact with your treatment.

**You should not take this treatment** if you are allergic to sorafenib or any of its components.

## How Is the Treatment Given?

Sorafenib is usually taken twice a day, but you may be given a different dosing schedule. Try to take sorafenib around the same time every day on an empty stomach, either one hour before a meal or two hours after a meal. Tablets should be swallowed whole with water. If you miss a dose, skip it and take the next dose as scheduled. Do not take two doses of sorafenib at the same time.

It is important to take sorafenib exactly as prescribed. Do not stop the medicine or change the dose without talking with your healthcare provider.

Store sorafenib at room temperature away from children and pets. If you take too much sorafenib, contact your healthcare provider, local poison control center or emergency room right away.

If you are given any medicine to take at home, do not share it with others. Sharing this medication with anyone else could be harmful.

## When Should I Call My Healthcare Provider?

Call your healthcare provider right away if you have any of the following symptoms:

- Shaking chills or fever 100.5 degrees F or higher
- Unusual bleeding, easy bruising or pinpoint red spots on your skin
- Vomiting that is severe or lasts several hours
- Painful or frequent urination or blood in your urine
- Diarrhea that causes an additional four bowel movements a day, diarrhea that lasts more than one day, diarrhea at night or diarrhea with fever, cramps or bloody stools
- Irregular or rapid heart beat, chest pain, chest tightness or shortness of breath
- Dizziness or feeling lightheaded
- Inability to eat or weight loss

## What Are the Possible Side Effects?

All drugs can cause side effects, but every person reacts differently to each drug. The following chart lists the possible side effects that can occur with your treatment, how to recognize and minimize symptoms and possible treatments. The side effects are grouped by how often the side effect occurs: Common (occurs in more than 25 percent of patients), Less Common (occurs in 5 to 25 percent of patients) or Rare (occurs in less than 5 percent of patients).

Side Effect	How to Minimize Side Effect	Possible Treatments
<p><b>Nausea/Vomiting (Common. Symptoms are generally mild.)</b></p> <ul style="list-style-type: none"> <li>• Feeling queasy or sick to your stomach</li> </ul>	<ul style="list-style-type: none"> <li>• Eat small, frequent meals and bland foods—such as bananas, rice, applesauce and toast.</li> <li>• Eat food cold or at room temperature so the smell of food will not bother you.</li> <li>• Avoid fried, spicy or fatty foods.</li> <li>• Eat and drink slowly.</li> <li>• Drink plenty of liquids during the day, but to avoid bloating, drink small amounts of liquid during meals.</li> </ul>	<ul style="list-style-type: none"> <li>• You will be given medicine to help reduce nausea and vomiting.</li> </ul>

Side Effect	How to Minimize Side Effect	Possible Treatments
<p><b>Diarrhea (Common. Symptoms are generally mild.)</b></p> <ul style="list-style-type: none"> <li>Loose or watery stools several times a day</li> <li>Abdominal cramping, gas and bloating</li> </ul>	<ul style="list-style-type: none"> <li>Eat small, frequent meals and bland foods—such as bananas, rice, applesauce and toast.</li> <li>Avoid caffeine; alcohol; raw fruits and vegetables; raw eggs; undercooked meats; spicy, fatty and greasy foods; milk and dairy products; foods that cause gas, such as beans and other legumes; high fiber and high-fat foods; foods left un-refrigerated for more than two hours (one hour for egg dishes and cream or mayonnaise-based foods); bulk laxatives; and stool softeners.</li> </ul>	<ul style="list-style-type: none"> <li>Drink eight to ten glasses of clear liquids every day.</li> <li>Your healthcare provider may prescribe medicine to help treat diarrhea.</li> </ul>
<p><b>Hand-Foot Syndrome (Common)</b></p> <ul style="list-style-type: none"> <li>Swelling or redness in the hands and feet that can prevent normal activity</li> <li>Cracked or peeling skin</li> <li>Tingling, numbness or pain in the hands or soles of the feet</li> </ul>	<ul style="list-style-type: none"> <li>Wear gloves to wash dishes.</li> <li>Avoid using harsh household cleaners.</li> <li>Avoid prolonged exposure to heat.</li> <li>Use creams or moisturizers regularly. Try wearing cotton gloves on your hands.</li> <li>Avoid using perfume, cologne or aftershave since these products can be irritating to the skin.</li> </ul>	<ul style="list-style-type: none"> <li>Your healthcare provider may prescribe a cream to help with skin reactions.</li> <li>Your healthcare provider may need to decrease the dose or delay further chemotherapy.</li> </ul>
<p><b>Alopecia or Hair Loss (Common)</b></p> <ul style="list-style-type: none"> <li>More than normal amount of hair loss in your brush, in the shower or on your pillow after sleeping</li> <li>Loss of body hair</li> </ul>	<p>Alopecia cannot be prevented but here are tips to help with hair loss:</p> <ul style="list-style-type: none"> <li>Use a soft hairbrush. Do not use brush rollers, color treat your hair or get a permanent.</li> <li>Avoid daily hair washing, use a mild shampoo and avoid using a hairdryer, or use a low setting if you must use one.</li> <li>Have your hair cut short; this will make it look fuller.</li> <li>Your insurance might cover a wig. If you would like a wig, ask your healthcare provider for a prescription for a "hair prosthesis". Your hair color and style can be better matched if you shop for a wig before losing a lot of hair.</li> <li>Use sunscreen or wear a hat or scarf to protect your scalp from the sun.</li> </ul>	
<p><b>Rash (Common)</b></p> <ul style="list-style-type: none"> <li>Usually mild and short-lived</li> <li>Generally appears on the arms and trunk (occasionally on the face)</li> <li>May be itchy</li> <li>May appear as a flat, discolored area on the skin or as a small raised bump</li> </ul>	<ul style="list-style-type: none"> <li>Avoid prolonged exposure to heat.</li> <li>Use creams or moisturizers regularly. Try wearing cotton gloves on your hands.</li> <li>Avoid using perfume, cologne or aftershave since these products can be irritating to the skin.</li> </ul>	<ul style="list-style-type: none"> <li>Your healthcare provider may prescribe creams (mild steroids, antihistamines or antibiotics) to help treat the rash.</li> <li>The rash may improve on its own without any treatment.</li> </ul>
<p><b>Mouth Sores and Pain (Less Common. Symptoms are generally mild.)</b></p> <ul style="list-style-type: none"> <li>Pain, swelling or redness of the mouth, tongue and throat</li> <li>"Coated tongue"</li> <li>Difficulty talking, swallowing or eating</li> <li>Bleeding ulcers and infection</li> </ul>	<ul style="list-style-type: none"> <li>Brush teeth two to four times a day using a soft bristle brush and fluoride toothpaste.</li> <li>Use non-waxed dental floss daily.</li> <li>Ask your healthcare provider to recommend a mouthwash that does not contain alcohol.</li> <li>Sip water during the day and use sugar-free candy or gum to keep your mouth wet.</li> <li>Eat food cold or at room temperature.</li> <li>Eat soft or pureed food.</li> <li>Avoid food that is acidic, spicy, salty, dry or rough, such as toast.</li> </ul>	<ul style="list-style-type: none"> <li>You may be given medicine to help treat pain.</li> <li>You may be given medicine to treat fungal or viral infections.</li> </ul>
<p><b>Constipation (Less Common)</b></p> <ul style="list-style-type: none"> <li>Difficulty passing stools</li> <li>Decrease in the normal frequency of bowel movements</li> <li>Small, hard, dry stools</li> <li>Bloating, gas, cramps and pain</li> </ul>	<ul style="list-style-type: none"> <li>Drink plenty of fluids to help loosen your bowels. Drink warm or hot liquids if you do not have mouth sores.</li> <li>Eat foods that are high in fiber, such as bran, vegetables, whole wheat breads, and fruit. Try prunes or prune juice, which act as laxatives.</li> <li>Exercise can help loosen bowels.</li> </ul>	<ul style="list-style-type: none"> <li>Your healthcare provider may recommend a stool softener.</li> </ul>

Side Effect	How to Minimize Side Effect	Possible Treatments
<b>Anorexia or Appetite Loss (Less Common)</b> <ul style="list-style-type: none"> <li>• Not having an appetite</li> <li>• Feeling too nauseated to eat</li> <li>• Metallic or medicinal taste</li> <li>• Change in taste causing dislike for certain foods</li> </ul>	<ul style="list-style-type: none"> <li>• Try eating six to eight small meals or snacks each day instead of three larger meals.</li> <li>• Vary your diet and try new foods and recipes.</li> <li>• Take a walk before meals, when possible. This may make you feel hungrier.</li> <li>• Eat with friends or family. When eating alone, listen to the radio or watch TV.</li> </ul>	<ul style="list-style-type: none"> <li>• Cook dinners ahead of time and freeze them in small portions so that cooking smells are minimized.</li> <li>• Let others help with food, but ask that foods be prepared in small portions that can be frozen. And don't hesitate to let them know which foods to avoid.</li> <li>• Add mild spices to change flavor.</li> <li>• It might be helpful to have a program, such as Meals on Wheels, deliver food to you.</li> </ul>
<b>Neuropathy (Less Common. Symptoms are generally mild.)</b> <ul style="list-style-type: none"> <li>• Numbness or tingling feeling in the hands or feet</li> <li>• Muscle cramps</li> <li>• Loss of balance</li> <li>• Difficulty buttoning buttons or picking up objects</li> <li>• Decreased awareness of heat or cold in fingertips and toes</li> <li>• Difficulty hearing</li> </ul>	<ul style="list-style-type: none"> <li>• Try to avoid the cold or extreme heat.</li> <li>• Wear mittens or gloves, socks and scarves.</li> <li>• If your fingers are numb, be careful with sharp objects.</li> <li>• Beware of hot coffee mugs, pots and pans and dishwasher—you may not feel the heat until you are burned.</li> <li>• If you feel unsteady, be careful on stairs and in the shower.</li> </ul>	<ul style="list-style-type: none"> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>
<b>Anemia (Rare)</b> <ul style="list-style-type: none"> <li>• Fatigue or weakness</li> <li>• Dizziness</li> <li>• Pale skin</li> <li>• Feeling out of breath</li> <li>• Feeling cold</li> </ul>	<ul style="list-style-type: none"> <li>• Plan rest periods throughout the day.</li> <li>• Organize daily activities so that you conserve your energy.</li> <li>• Try to eat a well balanced diet and drink plenty of fluids.</li> <li>• Stand up slowly to avoid getting dizzy.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given medicine to increase your red blood cell count.</li> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>
<b>Bleeding (Rare)</b> <ul style="list-style-type: none"> <li>• Unusual bleeding, easy bruising</li> <li>• Black or tar-like stools</li> <li>• Blood in your urine</li> <li>• Pinpoint red spots on your skin</li> <li>• Bleeding gums or nosebleeds</li> </ul>	<ul style="list-style-type: none"> <li>• Avoid aspirin and aspirin-like drugs, such as ibuprofen.</li> <li>• Use caution with sharp objects, such as razors and nail cutters.</li> <li>• Avoid activities that can cause cuts, bumps and bruises.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given medicine to increase your platelet count.</li> <li>• Your healthcare provider may decrease your dose or delay further treatment.</li> </ul>

## What Are the Other Possible Side Effects?

The following chart lists additional side effects found with this treatment. It does not list all possible side effects. For more information, talk with your healthcare provider.

Common Side Effects	Less Common Side Effects	Rare Side Effects
<ul style="list-style-type: none"> <li>• Fatigue</li> </ul>	<ul style="list-style-type: none"> <li>• Joint and muscle pain</li> <li>• Abdominal pain</li> <li>• Headache</li> <li>• Indigestion</li> <li>• Cough and shortness of breath</li> </ul>	<ul style="list-style-type: none"> <li>• Allergic reactions</li> </ul>

## Notes

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