Patient Education

Sorafenib (sor-AF-e-nib) for AML
(Acute Myeloid Leukemia)

Brand Name
Nexavar®

How is Sorafenib Administered?
Sorafenib comes as a 200 mg tablet, which is taken by mouth. The typical dose is (2) 200 mg tablets twice a day. Your doctor will determine the appropriate dose and schedule to treat your disease.

What is it used for?
Sorafenib is approved by the FDA (Food and Drug Administration) to treat kidney and liver cancers. Sorafenib is also used to treat leukemia that has a mutation in a gene called FLT-3. This is an off-label use because sorafenib is approved for use against other cancers, not for AML. The FDA allows doctors to use medications off label and it is a common practice when the cancer is hard to treat or has no standard therapy.

How does it Work?
Sorafenib is a type of targeted therapy, rather than traditional chemotherapy. Specifically, it is a tyrosine kinase inhibitor (TKI).

Cancer is a group of diseases in which abnormal cells multiply without control. Traditional chemotherapy agents identify cancer cells by their rapid rate of multiplication– and then attack those cells. Unfortunately, it also attacks normal cells that multiply quickly. Targeted therapy identifies other differences between normal cells and cancer cells, and then uses that difference to attack the cancer cells, sparing the normal cells.

Sorafenib works by blocking the action of the abnormal FLT-3 gene that signals leukemia cells to multiply.

What Should I Tell My Doctor Before I Begin Receiving Sorafenib?
Tell your doctor if you:
- have had an allergic reaction to sorafenib in the past
- are taking warfarin (Coumadin®), aspirin, products containing aspirin, over-the-counter pain medicines, vitamins, or herbal supplements
- have had surgery within the last 28 days or are planning any surgery
- have any chronic or non-healing wounds
- are pregnant or breastfeeding

This drug may interact with other medications or cause harmful side effects. Tell your doctor and pharmacist about all prescription or over-the-counter medications, vitamins, herbal or diet supplements that you are taking.
What Are Some Possible Side Effects I May Experience?

- **High blood pressure**, which usually starts within the first 6 weeks of treatment. We may add blood pressure medications to control this.
- **Skin rash with swelling, redness, pain and/or peeling on the palms of hands and soles of feet.** This is called hand-foot syndrome and is most likely to occur within the first 6 weeks of treatment. We may prescribe a variety of creams, ointments, lotions, and pain medications to manage this condition. If the side effect becomes severe, we may need to decrease your dose of sorafenib.
- **Low blood counts** (decreased red blood cells, white blood cells, and platelets), which increase your risk of fatigue, infections, and bleeding problems. If the condition is severe, we may need to lower your dose of sorafenib.
- **Delayed wound healing**
- **Diarrhea, constipation, vomiting, nausea, and decreased appetite**
- **Fatigue, weight loss, hair loss**
- **Shortness of breath and cough**
- **Numbness, tingling, or pain in hands and feet**
- **Abdominal, bone, muscle joint pain or headache**
- **Changes in thyroid function** have been reported. We may do blood tests to monitor your thyroid during sorafenib therapy.
- **Heart rhythm changes and chest pain** (uncommon)

How Can I Manage These Side Effects?

- If you develop high blood pressure, limit sodium (salt) in your diet.
- To help prevent hand-foot syndrome, modify your daily activities so your hands and feet are not exposed to high levels of friction or heat. Avoid rigorous exercise and hot water exposure. If you get hand-foot syndrome, consider getting padded insoles for your shoes or padded gloves for your hands.
- If your doctor says you are at risk for infection, stay away from large crowds or people with a cold, flu, or other infections. Talk to your doctor before you have any vaccinations. Wash your hands often.
- If you have a low platelet count, be aware that intercourse and other sexual activities may cause bleeding. Talk to your doctor or nurse about whether sexual activity is safe for you at this time. If intercourse is permitted, use a water-based lubricant and avoid forceful thrusting.
- If your blood counts drop, we may instruct you to use an electric razor, instead of a conventional razor blade, and to avoid contact sports or activities that could cause injury to reduce the risk of bleeding.
- Ask your doctor about medication to help prevent or lessen nausea and vomiting if you develop this side effect with sorafenib.
- Get plenty of rest and maintain good nutrition.
- Drink at least 2-3 quarts of fluid (especially water) every 24 hours, unless your doctor tells you otherwise.
- Acetaminophen and ibuprofen may help with discomfort from fever,
headache, and/or aches and pain but talk to your doctor before taking any of these medications.

- You may burn more easily, so avoid exposure to direct sunlight. Wear protective clothing and sunscreen with SPF of 30 or higher.
- Drinking alcoholic beverages should be kept to a minimum or avoided completely. Discuss this with your doctor.

### When Should I Call the Doctor?

**Call the clinic immediately if you experience:**

- fever of 100.5°F (38°C) or higher, chills, or any other signs of infection such as a sore throat, painful urination, or a skin wound that is red, swollen, painful, and/or warm to the touch
- anxiety, cold sweating, increased heart rate, shortness of breath, and/or severe pain in the chest, jaw, neck, back, or arms

**Call your doctor within 24 hours if you experience:**

- tingling or burning, redness, swelling of the hands or feet
- nausea that interferes with your ability to eat and is not relieved with prescription medications
- diarrhea or vomiting: 4+ episodes within a 24 hour period
- unusual bleeding or bruising, including dark black or tarry stools or blood in your stool or urine
- extreme fatigue that makes it difficult to care for yourself
- constipation that is not relieved by laxatives

### What Else Should I Know About Sorafenib?

- **Take sorafenib on an empty stomach.** Do not eat for 2 hours before taking your medication or for 1 hour afterwards. Food decreases the amount of drug that is absorbed from the stomach.

- **You must remember to take sorafenib every day,** as prescribed. Use a tablet box or a reminder system to help you remember.

- Your doctor will determine your exact dosage and schedule (400 mg is common). Do not stop taking sorafenib without notifying your doctor.

- If you miss a dose, take the next scheduled dose at its regular time; do not try to make up for the missed dose by taking extra doses.

- Both men and women should use effective methods of birth control while taking sorafenib. Barrier methods such as condoms are recommended during treatment. This drug may be harmful to a fetus.

- Tell your doctor if you are pregnant or may become pregnant prior to starting sorafenib.

- Breast feeding while on sorafenib is discouraged.

- You will have regularly scheduled lab tests while on this medication to watch your blood counts and your liver and kidney function.

- If you have any questions about sorafenib, talk to your doctor.