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## Sorafenib

pronounced as (soe raf' e nib)

### Why is this medication prescribed?

Sorafenib is used to treat advanced renal cell carcinoma (RCC; a type of cancer that begins in the kidneys). Sorafenib is also used to treat hepatocellular carcinoma (a type of liver cancer) that cannot be treated with surgery and a certain type of thyroid cancer that has spread to other parts of the body and cannot be treated with radioactive iodine. Sorafenib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps stop the spread of cancer cells.

### How should this medicine be used?

Sorafenib comes as a tablet to take by mouth. It is usually taken twice a day. Sorafenib is taken without food, 1 hour before or 2 hours after a meal. Take sorafenib at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take sorafenib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole with water. Do not split, chew, or crush them.

Your doctor may decrease your dose of sorafenib during your treatment, or may tell you to temporarily or permanently stop taking sorafenib for a period of time if you experience side effects. Be sure to tell your doctor how you are feeling during your treatment with sorafenib.

Continue to take sorafenib even if you feel well. Do not stop taking sorafenib without talking to your doctor.

Sorafenib is not available in pharmacies. You can only get sorafenib through the mail from a specialty pharmacy. Ask your doctor if you have any questions about receiving your medication.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

### Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking sorafenib,

- tell your doctor and pharmacist if you are allergic to sorafenib, any other medications, or any of the ingredients in sorafenib tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you have lung cancer and are receiving treatment with carboplatin (Paraplatin) and paclitaxel (Abraxane, Onxol, Taxol) or gemcitabine (Gemzar) and cisplatin (Platinol). Your doctor will probably tell you not to take sorafenib if you have lung cancer and you are receiving these medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: certain medications for arrhythmias such as amiodarone (Nexterone, Pacerone), dofetilide (Tikosyn), dronedarone (Multaq), procainamide, quinidine (in Nuedexta), and sotalol (Betapace, Sorine, Sotylize); anticoagulants (blood thinners) such as warfarin (Coumadin, Jantoven); carbamazepine (Equetro, Tegretol, Teril); dexamethasone; ibutilide (Corvert); irinotecan (Camptosar); neomycin; phenobarbital; phenytoin (Dilantin, Phenytek); rifabutin (Mycobutin); or rifampin (Rifadin, Rimactane). Many other medications may also interact with sorafenib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had high blood pressure, bleeding problems, chest pain, heart problems, QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death), low levels of potassium, calcium, or magnesium in your blood, an irregular heartbeat, heart failure, kidney problems other than kidney cancer, or liver problems other than liver cancer.
- tell your doctor if you are pregnant or plan to become pregnant. You will have to take a pregnancy test before starting treatment. If you are a woman who is able to become pregnant, you must use effective birth control during your treatment and for 6 months after your final dose. If you are male with a female partner who could become pregnant, you must use effective birth control during your treatment and for 3 months after your final dose. Talk to your doctor about birth control methods that will work for you. If you become pregnant while taking sorafenib, call your doctor immediately. Sorafenib may harm the fetus.
- tell your doctor if you are breastfeeding or plan to breastfeed. You should not breastfeed while taking sorafenib and for 2 weeks after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking sorafenib.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Sorafenib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- tiredness
- weakness
- skin redness
- hair loss
- itching
- dry or peeling skin
- loss of appetite
- constipation
- diarrhea
- dry mouth
- weight loss
- joint pain
- numbness, pain or tingling in hands or feet
- headache

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:**

- unusual bruising or bleeding
- black and/or tarry stools
- red blood in stools
- bloody vomit
- vomiting material that looks like coffee grounds
- fever
- severe stomach pain
- nausea
- vomiting
- chest pain
- shortness of breath
- dizziness or fainting
- excessive sweating
- fast, pounding, or irregular heartbeat
- sudden severe headache

- confusion
- changes in vision
- seizures
- rash
- redness, pain, swelling or blisters on the palms of the hands or soles of the feet
- skin blistering and peeling
- hives
- itching
- skin redness
- mouth sores
- dark urine
- yellowing of the skin or eyes
- pain in the upper right part of the stomach

Sorafenib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## **In case of emergency/overdose**

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

### Symptoms of overdose may include the following:

- diarrhea
- rash or other skin problems

### What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to sorafenib. Your doctor will also check your blood pressure every week during the first six weeks of your treatment and then from time to time as needed.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

### Brand names

- Nexavar®

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