

Important Safety Information

Do not take NEXAVAR if you have a specific type of lung cancer (squamous cell) and receive carboplatin and paclitaxel or if you are allergic to sorafenib or any of the other ingredients in NEXAVAR.

Before starting NEXAVAR, tell your doctor if you have: allergies, heart problems (including a problem called “congenital long QT syndrome”) or chest pain, bleeding or bruising problems, high blood pressure, any planned surgical procedures, lung cancer or are being treated for lung cancer, kidney problems in addition to kidney cancer, or liver problems in addition to liver cancer.

Tell your doctor if you are pregnant or plan to become pregnant and if you are breast-feeding or plan to breast-feed. It is not known if NEXAVAR passes into your breast milk. You and your doctor should decide if you will take NEXAVAR or breast-feed. You should not do both.

NEXAVAR may interact with certain other medicines and cause serious side effects so tell your doctor about all medicines you take including prescription and over-the-counter (OTC) medicines, vitamins, or herbal supplements. Especially tell your doctor if you are taking the following medicines: **warfarin (Coumadin, Jantoven®), neomycin, St. Johns Wort, dexamethasone, phenytoin (Fosphenytoin sodium, Dilantin, Phenytek), carbamazepine (Carbatrol, Equetro, Tegretol, Teril, Epitol), rifampin (Rifater, Rifamate, Rifadin, Rimactane), rifabutin (Mycobutin), phenobarbital.**

NEXAVAR may cause **serious** side effects, including:

- **decreased blood flow to the heart and heart attack.** Get emergency help right away and call your doctor if you have chest pain, shortness of breath, feel lightheaded or faint, have nausea or vomiting, or you are sweating a lot.
- **bleeding problems.** Bleeding is a common side effect of NEXAVAR that can be serious and sometimes lead to death. Tell your doctor if you have any bleeding or easy bruising while taking NEXAVAR.
- **high blood pressure.** High blood pressure is a common side effect of NEXAVAR and can be serious. Your blood pressure should be checked every week during the first 6 weeks of starting therapy and then regularly, thereafter. If your blood pressure is high, it should be treated.
- **a skin problem called hand-foot skin reaction.** This causes redness, pain, swelling, or blisters on the palms of your hands and soles of your feet. Your doctor may change your dose or stop treatment for a while.
- **serious skin and mouth reactions.** NEXAVAR can cause serious skin and mouth reactions which can be life-threatening. Tell your doctor if you have skin rash, blistering and peeling of the skin, blistering and peeling on the inside of your mouth.

- **an opening in the wall of your stomach or intestines (perforation of the bowel).** Tell your doctor right away if you get high fever, nausea, vomiting or abdominal (stomach) pain.
- **wound healing problems.** If you have a surgical or dental procedure, tell your doctor you are taking NEXAVAR. Your treatment may be stopped until after your surgery or until your wound heals.
- **changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life-threatening. Your doctor may do tests during your treatment with NEXAVAR to check the levels of potassium, magnesium, and calcium in your blood, and check the electrical activity of your heart with an ECG. Tell your doctor right away if you feel faint, lightheaded, dizzy, or feel your heart beating irregularly or fast while taking NEXAVAR.
- **inflammation of your liver (drug-induced hepatitis).** NEXAVAR may cause liver problems that may lead to liver failure and death. Your doctor may stop your treatment with NEXAVAR if you develop changes in certain liver function tests. Call your doctor right away if you develop yellowing of the skin or white part of your eyes (jaundice), dark “tea-colored” urine, light-colored bowel movements (stools), worsening nausea, worsening vomiting, abdominal pain.
- **birth defects or death of an unborn baby.** Avoid becoming pregnant while taking NEXAVAR and for at least 2 weeks after stopping your treatment. Men and women should use birth control during and at least 2 weeks after NEXAVAR therapy. Talk with your doctor about effective birth control methods. Call your doctor right away if you become pregnant.
- **change in thyroid hormone levels.** If you have differentiated thyroid carcinoma, you can have changes in your thyroid hormone levels when taking NEXAVAR. Your doctor should monitor thyroid hormone levels every month and may need to increase your dose of thyroid medicine.

The most common side effects with NEXAVAR include: diarrhea (frequent or loose bowel movements); tiredness; infection; hair thinning or patchy hair loss; rash; weight loss; loss of appetite; nausea; stomach (abdominal) pain; low blood calcium levels in people with differentiated thyroid cancer.

Tell your doctor if you have any side effects that bother you or do not go away. These are not all the possible side effects of NEXAVAR. Ask your doctor or pharmacist for more information.