What is NEXAVAR?
NEXAVAR is a prescription medicine used to treat:
- a type of liver cancer called hepatocellular carcinoma (HCC) that cannot be removed by surgery
- a type of kidney cancer called renal cell carcinoma (RCC)
- a type of thyroid cancer called differentiated thyroid carcinoma (DTC) that can no longer be treated with radioactive iodine and is progressing

It is not known if NEXAVAR is safe and effective in children.

Important Safety Information

Do not take NEXAVAR if you:
- are allergic to sorafenib or any of the other ingredients in NEXAVAR.
- have squamous cell lung cancer and receive carboplatin and paclitaxel.

Before taking NEXAVAR, tell your healthcare provider about all of your medical conditions, including if you:
- have heart problems including a condition called “congenital long QT syndrome”
- have chest pain
- have abnormal magnesium, potassium, or calcium blood levels
- have bleeding problems
- have high blood pressure
- plan to have any surgical procedures or have had recent surgery
- are pregnant or plan to become pregnant. NEXAVAR may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with NEXAVAR.
  For females who are able to become pregnant:
  o Your healthcare provider should do a pregnancy test before you start treatment with NEXAVAR.
  o Use effective birth control (contraception) during your treatment with NEXAVAR and for 6 months after the last dose of NEXAVAR.
  For males with female partners who are able to become pregnant:
  o Use effective birth control (contraception) during your treatment with NEXAVAR and for 3 months after the last dose of NEXAVAR.
  o NEXAVAR may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.
- are breastfeeding or plan to breastfeed. It is not known if NEXAVAR passes into your breast milk. Do not breastfeed during treatment with NEXAVAR and for 2 weeks after receiving the last dose of NEXAVAR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take the medicine warfarin.

What are the possible side effects of NEXAVAR?
NEXAVAR may cause serious side effects, including:
- decreased blood flow to the heart, heart attack and heart failure. Get emergency help right away if you get symptoms such as chest pain, shortness of breath, racing heartbeat, swelling in lower legs, feet and abdomen, feel lightheaded or faint, tiredness, nausea, vomiting, or sweat a lot.
- increased risk of bleeding. Bleeding is a common side effect of NEXAVAR that can be serious
and can lead to death. Tell your healthcare provider right away if you have any signs of bleeding during treatment with NEXAVAR:

- vomiting blood or if your vomit looks like coffee-grounds
- pink or brown urine
- red or black (looks like tar) stools
- coughing up blood or blood clots
- heavier than normal menstrual cycle
- unusual vaginal bleeding
- frequent nose bleeds
- bruising

**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 NEXAVAR. Your blood pressure should be checked regularly and any high blood pressure should be treated during treatment with NEXAVAR.

**skin problems.** A condition called hand-foot skin reactions and skin rash are common with NEXAVAR treatment and can be severe. NEXAVAR may also cause severe skin and mouth reactions that can be life threatening. Tell your healthcare provider if you have any of the following symptoms:

- skin rash
- skin redness
- pain or swelling
- blistering and peeling of your skin
- blistering and peeling on the inside of your mouth
- blisters on the palms of your hand or soles of your feet

**an opening in the wall of your stomach or intestines (gastrointestinal perforation).** Tell your healthcare provider right away if you get fever, nausea, vomiting or severe stomach (abdominal) pain.

**possible wound healing problems.** If you need to have a surgical procedure, tell your healthcare provider that you are taking NEXAVAR. NEXAVAR may need to be stopped until your wound heals after some types of surgery.

**changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life threatening. Your healthcare provider 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 electrocardiogram (ECG). Tell your healthcare provider right away if you feel faint, lightheaded, dizzy or feel your heart beating irregularly or fast during your treatment with NEXAVAR.

**liver problems (drug-induced hepatitis).** NEXAVAR may cause liver problems that may lead to liver failure and death. Your healthcare provider will do blood tests to check your liver function regularly during your treatment with NEXAVAR. Tell your healthcare provider right away if you develop any of the following symptoms:

- yellowing of your skin or the whites of your eyes
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- worsening nausea or vomiting
- pain on the right side of your stomach area
- bleeding or bruising more easily than normal
- loss of appetite

**change in thyroid hormone levels.** If you have differentiated thyroid cancer, you can have changes in your thyroid hormone levels during treatment with NEXAVAR. Your healthcare provider may need to change your dose of thyroid medicine during treatment with NEXAVAR. Your healthcare provider should check your thyroid hormone levels every month during treatment with NEXAVAR.

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

These are not all of the possible side effects of NEXAVAR. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.