

Patient Information
NEXAVAR® (NEX-A-VAR)
(sorafenib)
tablets, oral

Read this Patient Information before you start taking NEXAVAR and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is NEXAVAR?

NEXAVAR is an anticancer medicine used to treat a certain type of liver, kidney or thyroid cancer called:

- Hepatocellular carcinoma (HCC, a type of liver cancer), when it cannot be treated with surgery
- Renal cell carcinoma (RCC, a type of kidney cancer)
- Differentiated thyroid carcinoma (DTC, a type of thyroid cancer) that can no longer be treated with radioactive iodine and is progressing

NEXAVAR has not been studied in children.

Who should not take NEXAVAR?

Do not take NEXAVAR if you:

- are allergic to sorafenib or any of the other ingredients in NEXAVAR. See the end of this leaflet for a complete list of ingredients in NEXAVAR.
- have a specific type of lung cancer (squamous cell) and receive carboplatin and paclitaxel.

What should I tell my doctor before taking NEXAVAR?

Before you take NEXAVAR, tell your doctor if you:

- have any allergies
- have heart problems, including a problem called “congenital long QT syndrome”
- have chest pain
- have bleeding problems
- have high blood pressure
- plan to have any surgical procedures
- have lung cancer or are being treated for lung cancer
- have kidney problems in addition to kidney cancer
- have liver problems in addition to liver cancer
- are pregnant or plan to become pregnant. See **“What are the possible side effects of NEXAVAR?”**
- 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.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NEXAVAR and certain other medicines can interact with each other and cause serious side effects.

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**

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine. Do not take other medicines with NEXAVAR until you have talked with your doctor.

How should I take NEXAVAR?

- Take NEXAVAR exactly as prescribed by your doctor.
- The usual dose of NEXAVAR is 2 tablets taken 2 times a day (for a total of 4 tablets each day). Your doctor may change your dose during treatment, stop treatment for some time or completely stop treatment with NEXAVAR if you have side effects.
- Take NEXAVAR without food (at least 1 hour before or 2 hours after a meal).
- If you miss a dose of NEXAVAR, skip the missed dose, and take your next dose at your regular time. Do not double your dose of NEXAVAR.
- If you take too much NEXAVAR call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of NEXAVAR?

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 get symptoms such as chest pain, shortness of breath, feel lightheaded or faint, nausea, vomiting, or sweat 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 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 NEXAVAR. Your blood pressure should be checked regularly and any high blood pressure should be treated while you are taking NEXAVAR.
- **a skin problem called hand-foot skin reaction.** This causes redness, pain, swelling, or blisters on the palms of your hands or soles of your feet. If you get this side effect, your doctor may change your dose or stop treatment for some time.

- **serious skin and mouth reactions.** NEXAVAR can cause serious skin reactions which can be life-threatening. Tell your doctor if you have any of the following symptoms:
 - 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 severe stomach (abdominal) pain.
- **possible wound healing problems.** If you need to have a surgical procedure, tell your doctor 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 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 any of the following symptoms:
 - your skin or the white part of your eyes turns yellow (jaundice)
 - dark "tea-colored" urine
 - light-colored bowel movements (stools)
 - worsening nausea
 - worsening vomiting
 - abdominal pain
- **birth defects or death of an unborn baby.** Women should not get pregnant during treatment with NEXAVAR and for at least 2 weeks after stopping treatment. Men and women should use effective birth control during treatment with NEXAVAR and for at least 2 weeks after stopping treatment. Talk with your doctor about effective birth control methods. Call your doctor right away if you become pregnant during treatment with NEXAVAR.
- **change in thyroid hormone levels.** If you have differentiated thyroid cancer, you can have changes in your thyroid hormone levels when taking NEXAVAR. Your doctor may need to increase your dose of thyroid medicine while you are taking NEXAVAR. Your doctor 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 (abdominal) pain
- low blood calcium levels in people with differentiated thyroid cancer

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NEXAVAR?

- Store NEXAVAR tablets at room temperature between 68° F to 77° F (20° C to 25° C).
- Store NEXAVAR tablets in a dry place.

Keep NEXAVAR and all medicines out of the reach of children.

General information about NEXAVAR

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NEXAVAR for a condition for which it is not prescribed. Do not give NEXAVAR to other people even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about NEXAVAR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about NEXAVAR that is written for health professionals.

For more information, go to www.NEXAVAR.com, or call 1-866-639-2827.

What are the ingredients in NEXAVAR?

Active Ingredient: sorafenib tosylate

Inactive Ingredients: croscarmellose sodium, microcrystalline cellulose, hypromellose, sodium lauryl sulphate, magnesium stearate, polyethylene glycol, titanium dioxide and ferric oxide red.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Bayer HealthCare

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