

Storage

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) (see USP controlled room temperature). Store in a dry place.

17 PATIENT COUNSELING INFORMATION

See FDA-approved Patient Labeling (17.5)

17.1 Cardiac Ischemia; Infarction

Physicians should also discuss with patients that cardiac ischemia and/or infarction has been reported during NEXAVAR treatment, and that they should immediately report any episodes of chest pain or other symptoms of cardiac ischemia and/or infarction. [See *Warnings and Precautions* (5.1)]

17.2 Bleeding; Gastrointestinal Perforation

Physicians should inform patients that NEXAVAR may increase the risk of bleeding and that they should promptly report any episodes of bleeding.

Patients should be advised that cases of gastrointestinal perforation have been reported in patients taking NEXAVAR. [See *Warnings and Precautions* (5.2 and 5.5)]

17.3 Skin Reactions; Hypertension

Patients should be advised of the possible occurrence of hand-foot skin reaction and rash during NEXAVAR treatment and appropriate countermeasures.

Patients should be informed that hypertension may develop during NEXAVAR treatment, especially during the first six weeks of therapy, and that blood pressure should be monitored regularly during treatment. [See *Warnings and Precautions* (5.3 and 5.4)]

17.4 Birth Defects and Fetal Loss

Physicians should inform female patients that NEXAVAR may cause birth defects or fetal loss and that they should not become pregnant during treatment with NEXAVAR and for at least 2 weeks after stopping treatment. Both male and female patients should be counseled to use effective birth control during treatment with NEXAVAR and for at least 2 weeks after stopping treatment. Female patients should also be advised against breast-feeding while receiving NEXAVAR. [See *Warnings and Precautions* (5.11)]

17.5 FDA-approved Patient Labeling

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

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

What is the most important information I should know about NEXAVAR?

NEXAVAR may cause 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.

What is NEXAVAR?

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

1. Hepatocellular carcinoma (HCC, a type of liver cancer), when it can not be treated with surgery
2. Renal cell carcinoma (RCC, a type of kidney cancer)

NEXAVAR has not been studied in children.

What should I tell my doctor before starting NEXAVAR?

Tell your doctor about all of your health conditions, including if you:

- have any allergies
- have heart problems or chest pain
- have bleeding problems
- have high blood pressure

- have kidney problems in addition to kidney cancer
- **have liver problems in addition to liver cancer**
- are pregnant or planning to become pregnant. See “What is the most important information I should know about NEXAVAR?”
- are breast-feeding **or** planning 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 non-prescription 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 take warfarin (Coumadin®)*.**

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 do I take NEXAVAR?

- Take NEXAVAR exactly as prescribed by your doctor.
- The usual dose of NEXAVAR is 2 tablets taken two times a day (for a total of 4 tablets each day). Your doctor may change your dose during treatment or stop treatment for some time if you have side effects.
- Swallow NEXAVAR tablets whole with water.
- 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. Call your doctor right away if you take too much NEXAVAR.

What are 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, sweating a lot.
- **bleeding problems.** NEXAVAR may increase your chance of bleeding. Tell your doctor if you have any bleeding while taking NEXAVAR
- **high blood pressure.** 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 receiving 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.
- **perforation of the bowel.** Tell your doctor right away if you get high fever, nausea, vomiting, severe abdominal pain.
- **possible wound healing problems.** If you need to have a surgical or dental procedure, tell your doctor that you are taking NEXAVAR. NEXAVAR may need to be stopped until your wound heals after some types of surgery.
- **birth defects or death of an unborn baby.** See “What is the most important information I should know about NEXAVAR?”

Other side effects with NEXAVAR may include:

- rash, redness, itching or peeling of your skin
- hair thinning or patchy hair loss
- diarrhea (frequent or loose bowel movements)
- nausea or vomiting
- mouth sores
- weakness
- loss of appetite
- numbness, tingling or pain in your hands and feet
- abdominal pain
- tiredness
- weight loss

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

How should I store NEXAVAR?

- Store NEXAVAR tablets at room temperature between 59° to 86° F (15° to 30° C), 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 the 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 healthcare professionals. You can visit our website at www.NEXAVAR.com, or call 1-866-NEXAVAR (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.

Footnote: *Coumadin (warfarin sodium) is a trademark of Bristol-Myers Squibb Company

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