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Onyx Pharmaceuticals, Inc.,
2100 Powell Street, Emeryville, CA 94608

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Patient Information About:

NEXAVAR[®] (NEX-A-VAR)
(sorafenib)
tablets 200 mg

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 or healthcare professional 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.

Call your doctor right away if you become pregnant during treatment with NEXAVAR.

What is NEXAVAR?

NEXAVAR is an anticancer medicine to treat adults with kidney cancer called advanced renal cell carcinoma.

NEXAVAR has not been studied in children.

Who should not take NEXAVAR?

- **Do not take NEXAVAR if you are allergic to anything in it.** See the end of this leaflet for a complete list of ingredients.

What should I tell my doctor before starting NEXAVAR?

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

- have kidney problems in addition to kidney cancer
- have liver problems
- have high blood pressure

- **have bleeding problems**
- **have heart problems or chest pain**
- **are pregnant.** See “What is the most important information I should know about NEXAVAR?”
- **are breast-feeding.** NEXAVAR may harm your baby.

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 them to show to your doctor and pharmacist. Do not take other medicines with NEXAVAR until you have talked with your doctor.

If you need to have a surgical or dental procedure, tell your doctor that you are taking NEXAVAR.

How do I take NEXAVAR?

- Take NEXAVAR exactly as prescribed. You will stay on NEXAVAR as long as your doctor thinks it is helping you.
- The usual dose of NEXAVAR is 2 tablets taken twice a day (for a total of 4 tablets per day). Your doctor may adjust your dose during treatment or stop treatment for some time if you have side effects.
- Swallow NEXAVAR tablets whole with water.
- Take NEXAVAR on an empty stomach (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:

- **birth defects or death of an unborn baby.** See “What is the most important information I should know about 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 adjust your dose or stop treatment for some time.
- **high blood pressure.** Your blood pressure should be checked weekly during the first 6 weeks of starting NEXAVAR. High blood pressure should be monitored and treated during treatment with NEXAVAR.
- **perforation of the bowel. Talk to your doctor about this potential problem.**
- **heart problems.** Talk to your doctor about these potential problems.
- **bleeding problems.** NEXAVAR may increase your chance of bleeding.

Other side effects with NEXAVAR may include:

- rash, redness or itching of your skin
- hair thinning or patchy hair loss
- diarrhea (frequent and/or loose bowel movements)
- nausea and/or vomiting
- mouth sores
- weakness

- loss of appetite
- numbness, tingling or pain in your hands and feet

Talk with your doctor about ways to manage any side effects.

Uncommon side effects in patients taking NEXAVAR may include:

- severe high blood pressure requiring hospitalization and/ or leading to confusion, changes in vision and seizures
- the development of congestive heart failure

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° - 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 share your medicine with other people even if they have the same symptoms you have. It may harm them.

This 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.

Website and toll free number:

www.nexavar.com

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.

Rx Only

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

Manufactured by:



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