

Things to Know About NEXAVAR® (sorafenib) Tablets

This leaflet does not replace talking to your doctor. If you have questions about NEXAVAR, the first thing you should do is talk to your doctor.

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
- NEXAVAR is only available by prescription. You can get NEXAVAR from your doctor, hospital, or specialty pharmacy provider (SPP). You cannot go to a drug store and pick up NEXAVAR
- It is not known if NEXAVAR is safe and effective in children

How should I take NEXAVAR?

Recommended daily dose: 2 tablets, 2 times a day

Morning



2 NEXAVAR pills

Tablets not actual size.

Night



2 NEXAVAR pills

Take by mouth without food, 1 HOUR BEFORE or 2 HOURS AFTER eating



NEXAVAR is only available by prescription.

Important Safety Information

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 accompanying prescribing information for a complete list of ingredients in NEXAVAR
- Have a specific type of lung cancer (squamous cell) and receive carboplatin and paclitaxel

Before you start NEXAVAR, tell your doctor or nurse if you have any of these:

- Heart problems (including a condition called “congenital long QT syndrome”)
- Chest pain
- Abnormal magnesium, potassium, or calcium blood levels
- Bleeding problems
- High blood pressure
- Plan to have any surgical procedures or have had recent surgery

Also tell your doctor or nurse if you 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:
 - Your healthcare provider should do a pregnancy test before you start treatment with NEXAVAR
 - 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:
 - Use effective birth control (contraception) during your treatment with NEXAVAR and for 3 months after the last dose of NEXAVAR
 - 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
- 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.

How long will I take NEXAVAR?

- You will take NEXAVAR for as long as your doctor thinks it is helping you or until you get a side effect that makes your doctor change the amount of NEXAVAR that you take
- Your health care provider may change your dose, delay, or stop treatment if you have side effects

It is important to take an active role in your treatment and work with your health care team.

Please see additional Important Safety Information inside and accompanying full Prescribing Information.



What Are the Possible Side Effects of NEXAVAR® (sorafenib) Tablets?

If you know what to expect, you can watch for early signs of side effects, so you can tell your doctor about it. Some side effects, such as high blood pressure, HFSCR, and rash usually happen early in therapy.

Important Safety Information (continued)

What serious side effects might I have on NEXAVAR?

Possible serious side effects	What you should know or do
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 (perforation of the bowel)	Tell your doctor right away if you get fever, nausea, vomiting, or abdominal (stomach) pain.
Wound healing problems	If you need 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 any of the following symptoms: <ul style="list-style-type: none"> • Yellowing of the skin or white part of your eyes (jaundice) • 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 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

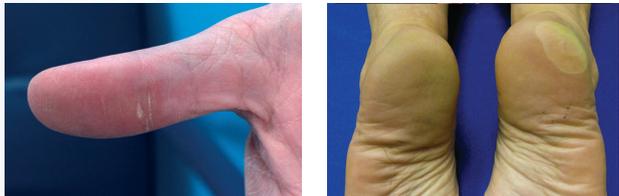
These are not all of the possible side effects of NEXAVAR. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How Might Some of My Side Effects Be Managed?

It is important to tell your doctor or health care team as soon as you notice any side effects or a change in your health.

Side effects

Management tips *(With your doctor's approval.)*

<p>Hand-foot skin reaction (HFSR) HFSR is a skin problem that causes redness, pain, swelling, or blisters on the palms of your hands or soles of your feet. Most of the time it happens in the first few weeks of treatment, but sometimes it happens later, after the sixth week. Your doctor may change your dose or stop treatment for a while.</p> 	<ul style="list-style-type: none"> • Use creams or lotions on your hands or feet • Soak skin in an Epsom salt bath with warm water • See a skin or foot doctor about sores or other problems with your feet • Use cotton socks and shoe pads • Wear loose clothes and shoes
<p>Loose bowel movements (diarrhea) Loose bowel movements may sound like they are not serious, but they can lead to a loss of water in your body (dehydration [de-hi-dra-tion]) and weight loss. Your doctor may give you medicine for diarrhea, but you must tell your doctor about the problem first.</p>	<ul style="list-style-type: none"> • Talk to your doctor about foods that are good for you • Eat a few small meals a day • Drink a lot of water or clear liquids, but not anything hot or cold • Take whatever medicine your doctor prescribes to help with diarrhea
<p>Feeling tired Treatment with NEXAVAR can make you feel more tired than normal (fatigue). This tired feeling will not always go away, even with a lot of rest or sleep. Tell your doctor about feeling tired. Your doctor will try to figure out what is making you feel tired. It could be NEXAVAR. It could be the cancer. It could be what you are eating. It could be not getting enough sleep.</p>	<ul style="list-style-type: none"> • Decide what is most important, do not try to do everything • Do things that need more energy in the morning, or at times when you feel you have more energy • Keep busy with things that relax you like games, music, reading, or visiting with friends • Keep moving during the day

See the *Your Guide to NEXAVAR (sorafenib)* brochure for detailed information about these and other common side effects.

Notes:

Your next appointment:

Date _____ Doctor's name _____

Time _____ Place _____

Please see additional Important Safety Information on the front and accompanying full Prescribing Information.



Important Contact Information and Resources

My phone numbers:

	Name	Telephone/Fax	E-mail
Oncology specialist	_____	_____	_____
Oncology nurse	_____	_____	_____
Hospital/clinic	_____	_____	_____
Specialty pharmacy provider (SPP)	_____	_____	_____
Specialty pharmacy provider (other contact)	_____	_____	_____
Other	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

Where can I find additional support while on NEXAVAR (sorafenib) therapy? www.nexavar-us.com

You may also be able to get help from the **REACH** program if you are eligible. It is free from the makers of NEXAVAR and may help you with your insurance problems and patient support. **REACH** may also provide information about independent programs to help eligible people pay for NEXAVAR. There is always someone at **REACH** to talk to, so call anytime:



1-866-NEXAVAR (1-866-639-2827)

Please see Important Safety Information on the front and inside, and accompanying full Prescribing Information.

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