

ORAL CANCER TREATMENT EDUCATION



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SORAFENIB

Name of your medication

Generic name — sorafenib (sor-A-feh-nib)
Brand name — Nexavar® (NEK-suh-var)

Common uses

Sorafenib is used to treat patients with unresectable hepatocellular carcinoma, advanced kidney cancer (renal cell carcinoma), or differentiated thyroid carcinoma.

Sorafenib may also be used for other treatments.

Dose and schedule

Taking sorafenib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of sorafenib is 400 milligrams (400 mg) to be taken by mouth at a scheduled time twice daily continuously without a scheduled off-treatment period.
- Sorafenib should be taken on an empty stomach (one hour before or two hours after a meal or snack) at the same time each day.
- Sorafenib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow sorafenib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of sorafenib:
 - **Do not** take an extra dose or two doses at one time. Simply take the next dose at the regularly scheduled time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.
- If you need to have surgery, tell your care provider you are taking sorafenib. Sorafenib may need to be stopped prior to and after major surgeries and until adequate wound healing.

Drug and food interactions

- Sorafenib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Talk with your care provider or pharmacist before taking new medications or supplements or receiving any vaccines.

Storage and handling

Handle sorafenib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store sorafenib at room temperature (68°F–77°F) in a dry location away from light and moisture.
- Keep sorafenib out of reach of children and pets.

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- ❑ Leave sorafenib in the provided packaging until it is ready to be taken.
- ❑ Whenever possible, give sorafenib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give sorafenib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the sorafenib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- ❑ If a daily pill box or pill reminder will be used, contact your care team before using:
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn
- ❑ If you have any unused sorafenib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of sorafenib.
- ❑ If you are traveling, put your sorafenib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Sorafenib

Below are common side effects that have been known to happen in about one third or more of patients taking sorafenib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains). • Avoid foods that cause gas (e.g., broccoli, beans). • Avoid lactose-containing foods (e.g., yogurt, milk). • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
Pain or discomfort in hands and/or feet	<p>Hand- foot skin reaction (HFSR) is a skin reaction that appears on the palms of the hands and soles of the feet. It can appear as a rash, calluses, peeling skin, and increased sensitivity to heat or a “pins and needles” sensation. Let your care provider know right away if you experience this side effect.</p> <p>To prevent HFSR, you can do the following:</p> <ul style="list-style-type: none"> • Keep hands and feet moisturized with a non-fragranced moisturizing cream. • Urea 10% or 20% cream may be helpful. • Avoid exposure to hot water on the hands and feet, in showers, or baths that may dry out the skin or doing dishes. • Avoid tight shoes or socks . • Avoid excess rubbing on hands and feet unless putting on lotion. • Wear gloves when working with your hands.
Hair loss (alopecia)	<p>Your hair will grow back after treatment is over.</p> <p>Some people choose to wear scarves, caps, or wigs. A short haircut prior to treatment may help with the stress of hair loss.</p>

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Possible Side Effect	Management
Changes in liver function	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
Changes in electrolytes and other laboratory values <ul style="list-style-type: none"> • Low albumin levels • Low phosphate levels • High lipase levels • High thyroid levels • Low calcium levels • High international normalized ratio levels • High amylase levels 	<p>Changes in some laboratory values may occur and should be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
Decreased appetite or weight loss	<p>Talk to your care provider if you notice a decrease in weight while taking this medication.</p> <p>When you do not feel like eating, try the following:</p> <ul style="list-style-type: none"> • Eat small, frequent meals instead of three large meals each day. • Keep snacks nearby so you can eat when you feel hungry. • Take liquid nutritional supplements. • Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.

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Possible Side Effect	Management
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently, and do not pick your nose. • Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include the following:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than five minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

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Possible Side Effect	Management
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	<p>Your hemoglobin should be monitored using a blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your healthcare provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
Increased blood pressure	<p>Routinely take your blood pressure. Record your blood pressure in a journal/diary and report these to your physician. Contact your healthcare provider for high blood pressure or if the following symptoms occur:</p> <ul style="list-style-type: none"> • Headache • Dizziness • Chest pain • Shortness of breath • Fluid retention, weight gain, or swelling
Rash or itchy skin	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am–4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on bottle. • Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
Abdominal pain	<p>Abdominal pain/discomfort may occur. Report any serious pain or symptoms to your care provider immediately.</p>

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Serious side effects of sorafenib

- You may be at a higher risk of bleeding while taking Sorafenib. Be sure to seek medical attention right away if you have any major bleeding. Also be sure to check for any signs of bleeding in your stool.
- Sorafenib can increase your risk of having a heart attack. Be aware of the signs of a heart attack and seek medical attention immediately at the first sign of a heart attack.
- Sorafenib may cause a condition called QT or QTc prolongation, which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast while taking sorafenib.
- Sorafenib can cause cuts or wounds to heal more slowly. Tell your care team if you have a wound that doesn't heal properly. Also tell your care team if you have planned surgery or dental procedure, as sorafenib should be stopped prior to your surgery. Your doctor may restart sorafenib after your surgical wound has healed.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Because sorafenib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take sorafenib, it is important to follow the instructions below every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or sorafenib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

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Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking sorafenib. Women of childbearing age and potential should use effective contraception during therapy and for 6 months after the last dose of sorafenib. Men with female partners of childbearing age and potential should use condoms (even after a vasectomy) during therapy and for 3 months after the last dose of sorafenib.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking sorafenib and for 2 weeks after the last dose of sorafenib.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining your sorafenib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.nexavar-us.com/?WHGRedir=1

Product prescribing information: http://labeling.bayerhealthcare.com/html/products/pi/Nexavar_PI.pdf

Product resources: www.nexavar-us.com/resources/?p=liver

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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