

Sunitinib (Sutent®)

Pronounced: soo-NI-ti-nib

Classification: Multikinase Inhibitor

About Sunitinib (Sutent®)

A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells. Sunitinib is a type of targeted therapy called a multikinase inhibitor. and it works by blocking two processes that allow cancer cells to grow. First, it interferes with a protein that promotes cell division. It also works by blocking the VEGF receptor, which is responsible for angiogenesis, or the development of a blood supply to the tumor. This removes the tumor's source of nutrients.

How to Take Sunitinib

Sunitinib comes as a capsule to take by mouth with or without food. Do not open the capsules. Your dose and schedule is determined by your healthcare provider and is based on the type of cancer you have. Take sunitinib at around the same time every day. If you miss a dose by less than 12 hours, take the missed dose right away. If you miss a dose by more than 12 hours resume your regular schedule. Do not take 2 doses at once.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, dexamethasone, carbamazepine, rifampin, phenytoin, St. John's wort, phenobarbital, ketoconazole, posaconazole, voriconazole. Be sure to tell your healthcare provider about all medications (prescription and over the counter) and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Sunitinib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible,

commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Sunitinib

There are a number of things you can do to manage the side effects of sunitinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Liver Toxicity

This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen, as these can be signs of liver toxicity.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

High Blood Pressure

High blood pressure (hypertension) occurred in clinical trials with sunitinib. Patients should have their blood pressure checked periodically during therapy. Any hypertension should be treated appropriately. In cases of severe hypertension, sunitinib should be stopped until blood pressure is controlled. Signs of hypertension to report to your team include: blurry vision, nosebleed, headache, and fatigue.

Diarrhea

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Muscle or Joint Pain/Aches

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- · Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these

symptoms).

- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Decrease in Appetite and Taste Changes

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

Mouth Ulcers (Mucositis)

Certain cancer treatments can cause sores or soreness in your mouth and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing regular mouth care can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

Hand Foot Syndrome

Hand foot syndrome (HFS) is a skin reaction that appears on the palms of the hands and/or the soles of the feet, as a result of certain chemotherapy agents being absorbed by the skin cells. HFS can begin as a mild tingling, numbness, pins-and-needles feeling, redness or pain or swelling of the hands and/or feet. This can then progress to painful swelling, blistering or peeling skin that can interfere with your ability to do normal activities. Be sure to let your oncology team know right away if you notice these symptoms, as they may need to adjust the chemotherapy dose or take a break to allow the skin to heal. Some tips to help prevent HFS include:

- Keep hands and feet clean and dry.
- Avoid tight shoes or socks.
- · Avoid activities that put pressure on the palms or soles for 1 week after treatment.
- Apply an alcohol-free moisturizer liberally and often. (Avoid moisturizers with perfumes or scents)
- Avoid very hot water for baths and showers.

Skin, Hair & Nail Changes

You may develop a yellow discoloration of the skin and/or hair. This is thought to be related to the yellow color of the medication. However, yellowing of the skin or eyes can be a sign of liver problems and should be reported to your healthcare team. Some patients may develop a rash, very dry, or itchy skin. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your care team can recommend a topical medication if itching is bothersome. Your nails may become dark, brittle or fall off. If your skin does crack or bleed or you lose a nail, be sure to keep the area clean to avoid infection. While receiving this medication, the hair on your head may become curly, fine or brittle. You may experience patchy hair loss or thinning. This tends to resolve once treatment is stopped.

Be sure to notify your care team of any rash that develops, as this can be a reaction and can become very severe. This includes blistering and peeling of your skin or the inside of your mouth. They can give you more tips on caring for your skin, hair and nails.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

Wound Healing

This medication can lead to slower or incomplete wound healing, such as a surgical wound not healing or staying closed. Therefore, it is recommended that the medication be discontinued 3 weeks prior to any surgery. The medication should not be restarted for at least 2 weeks after surgery or until any surgical incision is fully healed. If you have a surgical wound that has not healed or begins to have signs of infection (redness, swelling, warmth), report this to your healthcare team. You should inform the team performing the procedure and your oncology team of the upcoming procedure in advance of scheduling your procedure.

Bleeding & Stroke

Bleeding has occurred in patients taking this medication, including bleeding in the GI tract, lungs, urinary tract and brain (stroke). Let your healthcare provider know if you develop any bleeding, including nosebleeds, coughing up blood, vomiting blood or coffee ground appearing vomit, blood in the stool or black stools. If you experience changes in your speech or balance, confusion, difficulty walking, vision changes or numbness on one side of the body, call 911 right away.

Less common, but important side effects can include:

• *Heart Problems:* Some patients may develop heart failure or weakening of the heart muscle while taking sunitinib. Patients with a history of cardiac problems should have their heart function tested prior to starting this therapy, as well as during therapy if any symptoms arise. Symptoms include: shortness of breath, weight gain or swelling, cough or weakness, and should be reported to your healthcare team. This medication can cause heart rhythm abnormalities (arrhythmias) caused by a prolonged QT interval. If you are at risk for this, your healthcare provider will monitor you for heart problems through electrocardiograms. Notify your healthcare provider right away if you feel abnormal heartbeats or

if you feel dizzy or faint

- **Damage to Small Blood Vessels:** This medication can cause damage to small blood vessels called thrombotic microangiopathy (TMA), which can result in blood clots. Symptoms of TMA include fever, fatigue, bruising, swelling, confusion, vision loss, and seizures. Report any of these symptoms to your provider right away.
- **Tumor Lysis Syndrome:** If there are a large amount of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.
- Thrombotic Thrombocytopenic Purpura/Hemolytic Uremic Syndrome (TTP/HUS): This medication can cause a rare syndrome called thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS). Your healthcare team will monitor you for symptoms of TTP/HUS throughout your treatment with sunitinb. Notify your healthcare team if you have bruising or bleeding.
- Low blood sugar (hypoglycemia): Diabetic patients may need to monitor their glucose more often and/or change their diabetes medication.
- Proteinuria (Excess protein in the urine): Your care team will monitor for this.
- Swelling in the arms, feet, ankles, and legs: While swelling is a common reaction to this medication, it can be a sign of a serious heart problem and should be evaluated by your provider.
- **Changes in Hormone Levels:** This medication can affect the thyroid or adrenal glands, resulting in abnormal hormone levels, including hypothyroidism (under active thyroid) and hyperthyroidism (over active thyroid). Your doctor will perform blood tests to check the function of your thyroid and adrenal glands. Symptoms to report to your care provider include: tiredness, feeling hot or cold, change in your voice, weight gain or loss, hair loss, muscle cramps or weakness, lightheadedness, and excess urination.
- Posterior Reversible Encephalopathy Syndrome (PRES): In rare cases this medication has caused a neurological disorder called posterior reversible encephalopathy syndrome (PRES), also called reversible posterior leukoencephalopathy (RPLS). Symptoms of PRES/RPLS include headache, seizure, lethargy, confusion, blindness and other visual and neurological disturbances. Report any of these symptoms to your healthcare team immediately.
- Osteonecrosis of the Jaw: Osteonecrosis of the jaw (ONJ) is a rare side effect, however, it is important that you know about it and take steps to protect your dental health. It is most common in people who are also taking a bisphosphonate medication (for osteoporosis or bone metastases). The maxilla (upper jaw bone) and mandible (lower jaw bone) are normally covered by gum tissue. In the case of ONJ, this tissue is gone and the bone is exposed. Typical symptoms associated with ONJ are: pain, swelling or infection of the gums, loosening of the teeth, exposed bone (often at the site of a previous tooth extraction or procedure). Some patients may report numbness or tingling in the jaw or a "heavy" feeling jaw. ONJ may have no symptoms for weeks or months and may only be recognized by the presence of exposed bone. ONJ most often occurs soon after a dental procedure, though not always. Stop treatment with sunitinib at least 3 weeks prior to any dental procedures.
 - Prior to starting therapy, you should have a complete dental exam, cleaning, and removal of any teeth in poor health.
 - Dentures should be checked for proper fit.
 - Brush your teeth after meals and at bedtime with a soft brush. Ask your care team if you are able to floss, and if you are, floss gently once a day.
 - Check your teeth and gums in a mirror daily for any sores, swelling, loose teeth, pain or numbness, or other changes and report these to your dentist or oncology team immediately.

Reproductive Changes

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for 4 weeks after your last dose for women and for 7 weeks for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication or for 4 weeks after your last dose.

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