

Sunitinib (Sutent®)

About This Drug

Sunitinib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Decrease in the number of platelets. This may raise your risk of bleeding.
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea and vomiting (throwing up)
- Indigestion
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds or any other unusual bleeding
- Tiredness and weakness
- Decreased appetite (decreased hunger)
- Weight loss
- Headache
- Changes in the way food and drinks taste
- Hand-and-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.
- High blood pressure

Note: Each of the side effects above was reported in 25% or greater of patients treated with sunitinib. Not all possible side effects are included above.

Warnings and Precautions

- Changes in your heart function which can be life-threatening. This drug may increase your risk of heart attack and abnormal heart beat. You may also be at risk of congestive heart failure. You may be short of breath. Your arms, hands, legs and feet may swell.
- Severe high blood pressure
- Severe abnormal bleeding which can be life-threatening

- Damage to small blood vessels which can cause bleeding and blood clots and can be life-threatening.
- Increased protein in your urine which can affect how your kidneys work and cause renal failure, which can be life-threatening
- Tumor lysis syndrome: This drug may act on the cancer cells very quickly. This may affect how your kidneys work.
- Changes in your liver function, which can cause liver failure and be life-threatening
- Changes in your thyroid function
- Blood sugar levels may decrease
- Severe allergic skin reaction which can rarely be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Osteonecrosis of the jaw. This is a breakdown of the jaw bone.
- Slow wound healing

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- Sunitinib may cause slow wound healing. It should not be given before surgery. If you must have emergency surgery or have an accident that results in a wound, tell the doctor that you are on sunitinib.

How to Take Your Medication

- Swallow the medicine whole with or without food.
- **Missed dose:** If you miss a dose by less than 12 hours, take it as soon as you think about it. If you miss a dose by more than 12 hours, then skip the missed dose and take your next dose at the regular time and contact your physician.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- To decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.

- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Manage tiredness by pacing your activities for the day. Be sure to include periods of rest between energy-draining activities.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- Include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your doctor or nurse about medicines that are available to help stop or lessen diarrhea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Moisturize your skin several times day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- Tell your cancer doctor if you have any problems with your teeth or jaw before you start this drug. It is important that your dentist knows that you are on this drug. Give your dentist and your cancer doctor each other's name and phone number so they may call each other if they have any questions.

Food and Drug Interactions

- Avoid grapefruit or drink grapefruit juice while taking this medicine. Grapefruit and grapefruit juice may raise the levels of sunitinib in your body. This could make side effects worse.

- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) you are taking before starting this medicine as there are known drug interactions with sunitinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking sunitinib as this may lower the levels of the drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Headache that does not go away
- Blurry vision or other changes in eyesight
- Easy bleeding or bruising
- Blood in your urine, vomit (bright red or coffee-ground) and/or stools (bright red, or black/tarry)
- Coughing up blood
- Wheezing or trouble breathing
- Swelling in your arms, hands, legs or feet
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Unexplained weight gain
- Pain in your abdomen that does not go away
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Weight gain of 5 pounds in one week (fluid retention)
- Decreased urine, or very dark urine
- Abnormal blood sugar
- Signs of low blood sugar: headache, feeling dizzy, confusion, feeling hungry, fast heartbeat, sweating and/or feeling jittery
- Signs of tumor lysis: Confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures

- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- New rash and/or itching that is not relieved by prescribed medicines
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- Signs of osteonecrosis of the jaw: pain, swelling or infection of the gums, loose teeth, poor healing of the gums, numbness or the feeling that your jaw is heavy
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 4 weeks after treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 7 weeks after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 4 weeks after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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