



Sunitinib

(soo ni' ti nib)

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Why is this medication prescribed?

Sunitinib is used to treat gastrointestinal stromal tumors (GIST; a type of tumor that grows in the stomach, intestine (bowel), or esophagus (tube that connects the throat with the stomach) in people with tumors that were not treated successfully with imatinib (Gleevec) or people who cannot take imatinib. Sunitinib is also used to treat advanced renal cell carcinoma (RCC, a type of cancer that begins in the cells of the kidneys). Sunitinib is in a class of medications called multikinase inhibitors. It works by blocking the action of the abnormal protein that signals cancer cells to multiply. This helps stop or slow the spread of cancer cells and may help shrink tumors.

How should this medicine be used?

Sunitinib comes as a capsule to take by mouth with or without food. It is usually taken once a day for 4 weeks (28 days) followed by a 2-week break before beginning the next dosing cycle. Take sunitinib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take sunitinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not split, chew, or crush them. Do not open the capsules.

You may need to take one or more capsules at a time depending on your dose of sunitinib.

Your doctor may gradually increase or decrease your dose of sunitinib during your treatment. This depends on how well the medication works for you and the side effects you experience. Talk to your doctor about how you are feeling during your treatment. Continue to take sunitinib even if you feel well. Do not stop taking sunitinib without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking sunitinib,

- tell your doctor and pharmacist if you are allergic to sunitinib, mannitol, or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: certain antibiotics such as clarithromycin (Biaxin, in Plevpac), erythromycin (E.E.S., E-Mycin, Erythrocin), moxifloxacin (Avelox), rifampin (Rifadin, Rimactane), rifabutin (Mycobutin), rifapentine (Priftin), sparfloxacin (Zagam) (not available in the US), telithromycin (Ketek), and troleandomycin (TAO) (not available in the US); anticoagulants ('blood thinners') such as warfarin (Coumadin); antifungals such as itraconazole (Sporanox), ketoconazole (Nizoral), and voriconazole (Vfend); bevacizumab (Avastin), certain calcium channel blockers such as diltiazem (Cardizem, Dilacor, Tiazac, others) and verapamil (Calan, Isoptin, Verelan); cimetidine (Tagamet); cisapride (Propulsid); dexamethasone (Mymethasone); certain medications for depression such as fluvoxamine and nefazodone; certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) including atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); medications for irregular heartbeat including amiodarone (Cordarone), disopyramide (Norpace), dofetilide (Tikosyn) procainamide (Procanbid, Pronestyl), quinidine (Quinidex), and sotalol (Betapace, Betapace AF); certain medications for seizures such as carbamazepine (Carbatrol, Equetro, Tegretol), phenobarbital, and phenytoin (Dilantin, Phenytek); pimozone (Orap); and thioridazine (Mellaril). Other medications may also interact with sunitinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor and pharmacist what herbal products you are taking, especially St. John's wort. Your doctor will probably tell you not to take St. John's wort while taking sunitinib.
- tell your doctor if you have or have ever had a bleeding problem; angina (chest pain); a slow, fast, or irregular heartbeat; a heart attack; heart bypass surgery; heart failure; high blood pressure; pulmonary embolism (PE; blood clot in the lungs); seizures; a stroke or transient ischemic attack (TIA, mini-stroke); or heart, kidney, liver, or thyroid disease.
- tell your doctor if you are pregnant, could be pregnant, or plan to become pregnant. You should not become pregnant while you are taking sunitinib. Talk to your doctor about birth control methods that you can use during your treatment. If you become pregnant while taking sunitinib, call your doctor immediately. Sunitinib may harm the fetus.
- tell your doctor if you are breast-feeding. You should not breast-feed while you are taking sunitinib.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking sunitinib.
- you should know that sunitinib may cause your skin to turn yellow and your hair to lighten and lose color. This is probably caused by the yellow color of the medication and is not harmful or painful. Your natural skin and hair color will likely return after you stop taking sunitinib.
- you should know that sunitinib may cause high blood pressure. Your blood pressure should be checked regularly while you are taking sunitinib.

What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. Tell your doctor or nurse about the missed dose.

What side effects can this medication cause?

Sunitinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- extreme tiredness
- weakness
- nausea
- vomiting
- diarrhea
- constipation
- heartburn
- gas
- white patches or sores on the lips or in the mouth and throat
- pain, irritation, or burning sensation of the lips, tongue, mouth or throat
- dry mouth
- change in the way things taste
- loss of appetite
- weight loss
- hair loss
- thin, brittle fingernails or hair
- slow speech
- depression
- dryness, thickness, cracking, or blistering of skin on the palms of the hands and the soles of the feet
- rash
- muscle or limb pain
- pain, burning, numbness, or tingling in the hands or feet
- unusual discomfort in cold temperatures

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- unusual bruising or bleeding
- black and tarry stools
- red blood in stools
- bloody vomit
- vomit that looks like coffee grounds
- stomach pain or swelling
- fever
- chills
- swelling, tenderness, warmth, or redness of a leg
- swelling of the feet or ankles
- rapid, irregular, or pounding heartbeat
- chest pain
- shortness of breath
- weight gain
- difficulty falling asleep or staying asleep
- coughing up pink or bloody mucus
- increased urination, especially at night
- sudden severe back, stomach, or leg pain

Sunitinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to sunitinib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Sutent®

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