

Sutent[®] (sunitinib malate) for Kidney Cancer

Sutent is a medication used to treat adult patients with kidney cancer that has been surgically removed and at high risk of recurrence, or advanced kidney cancer that has spread to other organs.

Dosage: 50 mg once a day

How supplied: 12.5mg, 25mg, 37.5mg, 50mg

Storage: Room temperature between 59°F to 86°F (15°C to 30°C)

Route of Administration: Sutent is a capsule(s) taken by mouth

Schedule: Once a day for 4 weeks of treatment followed by 2 weeks off treatment.

How should I take Sutent?

- Take it exactly the way your healthcare provider tells you
- Your doctor may change your dose if needed
- Do not open a Sutent capsule
- If you miss a dose, take it as soon as you remember. You can take it up to 12 hours after you normally take it. If more than 12 hours, skip the dose and take it as usual the next day
- If you vomit after taking a dose, do not take an additional dose
- If you think you have taken an extra dose of this medication, call your healthcare provider right away

Dietary restrictions: Can be taken with or without food

- You should not drink grapefruit juice or eat grapefruit during your treatment with Sutent. That may increase the amount of Sutent in your body to a harmful level.

What is the most important information I should know about Sutent?

- Sutent can cause serious liver problems including death. Tell your healthcare provider if you develop any of the following signs and symptoms such as itching, yellow eyes or skin, dark urine, and/or pain/discomfort in the right upper stomach area
Your healthcare provider should do blood tests to check liver function before you start taking Sutent and during treatment

I should tell my healthcare provider if I:

- have any heart problems
- have high blood pressure
- have thyroid problems

- have a history of low blood sugar or diabetes
- have kidney function problems (other than cancer)
- have liver problems
- have any bleeding problem
- plan to have surgery or dental procedures. You should stop taking Sutent at least 24 hours before planned surgery. Your healthcare provider or dentist should talk to your doctor who prescribed Sutent before any surgical or dental procedure
- have seizures
- have or have had pain in the mouth, teeth or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth
- have any other medical conditions

For females, tell your doctor if you:

- are pregnant or plan to become pregnant. Taking Sutent during pregnancy may cause the death of an unborn baby or birth defects. You should not become pregnant while you are taking Sutent.
- are able to become pregnant. You should use effective birth control during your treatment and for 4 weeks after your last dose of Sutent. Talk to your doctor about birth control methods to prevent pregnancy while you are taking Sutent.
- are breast-feeding or plan to breast-feed. It is not known if Sutent passes into your breast milk. You and your doctor should decide if you will take Sutent or breast-feed. You should not do both.

For males:

- use effective birth control during your treatment and for 7 weeks after your last dose of Sutent. Sutent may cause fertility problems in males and females. Tell your health provider if this is a concern for you.
- talk to your doctor about birth control methods.
- if your female partner becomes pregnant while you are taking Sutent, tell your doctor right away.

Tell your healthcare provider at each visit about all the medications you take including prescription and non-prescription medicine, vitamins, and herbal supplements. Sutent may affect the way other medicines work and other medicines may affect how Sutent works. Using Sutent with certain other medicines can cause serious side effects.

Especially tell your doctor if you take or have taken:

- Medicine for osteoporosis:
 - Risedronate (Actonel)
 - Pamidronate (Aredia)
 - Ibandronate (Boniva)
 - Etidronate (Didronel)
 - Alendronate (Fosamax)

- Zoledronate (Reclast or Zometa)
- Tiludronate (Skelid)
- Medicine for:
 - high blood pressure (some drugs)
 - infections (some antibiotics)
 - HIV (some drugs for treatment)
 - depression (some drugs)
 - Irregular heartbeats (some drugs)
 - Herbal supplements like St. John's Wort

Ask your doctor or pharmacist if you are not sure if your medicine is one listed above. If you are taking any medicines for the conditions listed above, your doctor might need to prescribe a different medicine or your dose of Sutent may need to be changed. Talk with your doctor before you start taking any new medicine.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of Sutent?

Common Side effects of Sutent include:

- The medicine in Sutent is yellow, and it may make your skin look yellow
- Your skin and hair may also get lighter (white) in color
- Tiredness
- Weakness
- Fever
- Gastrointestinal symptoms, including diarrhea, nausea, vomiting, mouth sores, upset stomach, abdominal pain, and constipation. Talk with your healthcare provider about ways to handle these problems.
- Rash or other skin changes, including drier, thicker or cracking skin
- Blisters or a rash on the palms of your hands and soles of your feet
- Taste changes
- Loss of appetite
- Pain or swelling in your arms or legs
- Cough
- Shortness of breath
- Bleeding, such as nosebleeds or bleeding from cuts

Call your healthcare provider if you have any swelling or bleeding during treatment with Sutent.

These are not all of the possible side effects of Sutent. Tell your healthcare provider if you have any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. For more information, ask your healthcare provider or pharmacist.

Sutent may cause serious side effects including:

- **Heart Problems.** Heart problems may include heart failure, heart attack and heart muscle problems (cardiomyopathy) that can lead to death. Tell your healthcare provider if you feel very tired, are short of breath, or have swollen feet and ankles.
- **Abnormal heart rhythm changes.** Your healthcare provider may do electrocardiograms and blood tests to watch for these problems during your treatment with Sutent. Tell your healthcare provider if you feel dizzy, faint, or have abnormal heartbeats while taking Sutent.
- **High Blood Pressure.** Your healthcare provider may check your blood pressure during treatment with Sutent. Tell your healthcare provider if your blood pressure is high, or you have a severe headache, lightheadness, dizziness or change in vision. Your healthcare provider may prescribe medicine for you to treat high blood pressure if needed.
- **Bleeding sometimes leading to death.** Tell your healthcare provider right away if you have any of these symptoms or a serious bleeding problem during treatment with Sutent.
 - Painful, swollen stomach (abdomen)
 - Vomiting blood
 - Black, sticky stools
 - Bloody urine
 - Headache or change in your mental status
- **Serious stomach and intestinal problems that can sometimes lead to death.** Tears in the stomach or intestine (perforation), or an abnormal opening between the stomach and intestine (fistula) may occur. Get medical help right away if you have abdominal pain that does not go away.
- **Jaw-bone problems (osteonecrosis).** Severe jaw problems may happen when you take Sutent. Your healthcare provider should examine your mouth before you start Sutent. Your healthcare provider may tell you to see your dentist before you start Sutent.
- **Tumor lysis syndrome (TLS)** TLS is caused by the fast breakdown of cancer cells and may lead to death. TLS may cause you to have nausea, shortness of breath, irregular heartbeat, clouding of urine and tiredness associated with abnormal laboratory test results (high potassium, uric acid and phosphorus levels and low calcium levels in the blood) that can lead to changes in kidney function and acute kidney failure.
- **Thrombotic microangiopathy (TMA)** Damage to the smallest blood vessels may occur. TMA is a condition involving injury to the vessels and resulting blood clots and is accompanied by injury to red blood cells leading to a decrease in red cells and a decrease in cells that involved with clotting. TMA may harm organs such as the brain and kidneys.

Symptoms of TMA may include fever, fatigue, tiredness, bruising, swelling, confusion, vision loss and seizures. Your healthcare provider may tell you to stop taking Sutent.

- **Protein in your urine.** Your healthcare provider will check you for this problem. If there is too much protein in your urine, your healthcare provider may tell you to stop taking Sutent.
- **Serious skin and mouth reactions.** Sutent can cause serious skin reactions that can cause death. This can include rash, widespread blistering or peeling of the skin and blistering and peeling of the inside of your mouth. If you develop a rash or these skin symptoms, tell your healthcare provider immediately.
- **Hormone problems, including thyroid and adrenal gland problems.** Your healthcare provider may do tests to check your thyroid and adrenal gland function before and during Sutent treatment. Tell your doctor if you have any of the following signs or symptoms during treatment with Sutent:
 - Tiredness that worsens and does not go away
 - Loss of appetite
 - Heat intolerance
 - Feeling nervous or agitated, tremors
 - Sweating
 - Cold intolerance
 - Nausea, vomiting, diarrhea
 - Fast heart rate
 - Weight gain or weight loss
 - Feeling depressed
 - Irregular menstrual periods or no menstrual periods
 - Headache
 - Hair loss
- **Low blood sugar (hypoglycemia)** Low blood sugar can happen with Sutent, and may cause you to become unconscious or you may need to be hospitalized. Low blood sugar with Sutent may be worse in people who have diabetes and take anti-diabetic medicines. Signs and symptoms of low blood sugar may include:
 - headache
 - drowsiness
 - weakness
 - dizziness
 - confusion
 - irritability
 - hunger
 - fast heart beat
 - sweating
 - feeling jittery

General information about Sutent: Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Sutent for a condition for which it was not prescribed. Do not give Sutent to other people, even if they have the same symptoms you have. It may harm them. This Patient Information sheet summarized the most important information about Sutent. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Sutent that is written for healthcare professionals.

Patient Assistance Program: Pfizer RxPathways is a reimbursement program from Pfizer. To enroll, speak to your healthcare provider, call 1-866-706-2400, or go to www.pfizerRxpath.com

Resources: Pfizer Labs, Division of Pfizer Inc
1-877-5-SUTENT
www.sutent.com

Adapted from the Sutent (Sunitinib malate) package insert. Pfizer, November 2017

KCA disclaimer statement: you should rely primarily upon your doctor for medical information.

www.kidneycancer.org