Sutent® (sunitinib malate) for Kidney Cancer

Sutent is a medication used to treat advanced kidney cancer in adults

Dosage: 50mg once a day

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

Storage: Room temperature

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

Schedule: Once a day for 28 days, followed by 14 days off drug

How should I take Sutent?

- Take it exactly the way your healthcare provider tells you
- Take it with or without food
- Do not open the Sutent capsules
- 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 at 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 or hormone problems
- plan to have surgery
- have kidney function problems (other than cancer)
- have liver problems
• have any bleeding problems
• 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
• am or become pregnant or plan to become pregnant. Sutent can harm your unborn baby. You should not become pregnant while you are taking Sutent
• am breast-feeding or plan to breast-feed. It is not known if Sutent passes into your breast milk. You and your healthcare provider should decide if you will take Sutent or breast-feed. You should not do both.

Tell all of your healthcare providers and dentist that you are taking Sutent. They should talk to the healthcare provider who prescribed Sutent before you have any surgery, or medical or dental procedure.

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

• some drugs used to treat high blood pressure
• some antibiotics (used to treat infections)
• some drugs used to treat HIV
• some drugs used to treat depression
• drugs used to treat irregular heart beats
• herbal supplements like St. John’s Wort

What are the possible side effects of Sutent?

Sutent may cause serious side effects including:

• Heart Problems. Heart problems may include heart failure and heart muscle problems (cardiomyopathy) that can lead to death. Tell your healthcare provider if you feel very tired, are short of breath, have swollen feet or ankles.
• Abnormal heart rhythm changes. Your healthcare provider may do electrocardiograms and blood tests to watch for 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. 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.
  o Painful, swollen stomach (abdomen)
  o Vomiting blood
  o Black, tarry stools
  o Bloody urine
  o Headache or change in mental status
Your healthcare provider can tell you other symptoms to watch for.
• Jaw-bone problems (osteonecrosis) Severe jaw bone problems may happened when you take Sutent. Your healthcare provider should examine your mouth before you start Sutent. You may need to see your dentist before starting Sutent.
• Tumor lysis syndrome (TLS) TLS is caused by 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.
• Protein in your urine. Your healthcare provider can do tests to check for this.
• 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 is you have any of the following signs or symptoms during treatment with Sutent:
  o Tiredness that worsens and does not go away
  o Loss of appetite
  o Heat intolerance
  o Feeling nervous or agitated, tremors
  o Sweating
  o Cold intolerance
  o Nausea, vomiting, diarrhea
  o Fast heart rate
  o Weight gain or weight loss
  o Feeling depressed
  o Irregular menstrual periods or no menstrual periods
  o Headache
  o Hair loss
• Wound healing. Delayed or impaired healing

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 in color.
• Tiredness
• Weakness
• Fever
• Gastrointestinal symptoms, including diarrhea, nausea, vomiting, mouth soreness, upset stomach, abdominal pain, and constipation. Talk with your healthcare provider about to handle these problems.
• Rash or other skin changes, including drier, thicker, or cracking skin.
• Blisters or rash on the palms of your hands and/or 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.

**Patient Assistance Program:** FIRST RESOURCE is a reimbursement program from Pfizer. To enroll, speak to your healthcare provider, call 1-877-744-5675, or go to [www.sutent.com](http://www.sutent.com) Click on “help paying for Sutent”.

**Resources:** Pfizer 1-877-744-5675
www.sutent.com

Adapted from the Sutent (Sunitinib malate) package insert. Pfizer, December 2014

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

[www.kidneycancer.org](http://www.kidneycancer.org)