

PATIENT INFORMATION

SUTENT

(su TENT)

Read the patient information leaflet that comes with SUTENT before you start taking it. Read the leaflet each time you get a refill. There may be new information. This leaflet does not replace talking with your doctor about your condition or treatment. If you have any questions about SUTENT, ask your doctor or pharmacist.

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

- **SUTENT may harm an unborn baby (cause birth defects).** Do not become pregnant. If you do become pregnant, tell your doctor right away. Stop taking SUTENT.

What is SUTENT?

SUTENT is a medicine that treats 2 kinds of cancer.

1. **GIST (gastrointestinal stromal tumor).** This is a rare cancer of the stomach, bowel, or esophagus. SUTENT is used when the medicine Gleevec® (imatinib mesylate) did not stop the cancer from growing OR when you cannot take Gleevec®.
2. **Advanced kidney cancer** (advanced renal cell carcinoma or RCC).

SUTENT may slow or stop the growth of cancer. It may help shrink tumors. SUTENT has not been studied in children.

What should I tell my doctor before taking SUTENT?

Tell your doctor about all your medical conditions. **Be sure to tell your doctor if you:**

- are pregnant, could be pregnant, or plan to get pregnant. SUTENT may harm an unborn baby.
- are breast-feeding. Do not breast-feed while you are being treated with SUTENT.
- have any heart problems
- have high blood pressure
- have kidney function problems (other than cancer)
- have liver problems
- have any bleeding problem
- have seizures

SUTENT and other medicines

Tell your doctor about all your medicines. Include **prescription medicines**, over-the-counter drugs, vitamins, and herbal products. Some medicines can react with SUTENT and cause serious side effects.

Especially tell your doctor if you take:

- St. John's Wort. **Do not take St. John's Wort while taking SUTENT.**
- Dexamethasone (a steroid)
- Medicine for:
 - tuberculosis (TB)
 - seizures (epilepsy)
 - infections (antibiotics)
 - fungal infections (antifungals)
 - depression
 - HIV (AIDS)

Keep a list of your medicines. Show it to your doctor or pharmacist. Talk with your doctor before starting any new medicines.

What are possible side effects of SUTENT?

Possible serious side effects include:

- **Heart Problems.** Tell your doctor if you feel very tired, are short of breath, or have swollen feet and ankles.
- **Rare life-threatening events:** hole in stomach or bowel wall (perforation) or bleeding from the tumor. Both of these side effects could cause symptoms such as painful, swollen abdomen, vomiting blood, and black, sticky stools. Your doctor can tell you other symptoms to watch for.
- **Increased blood pressure.** Your doctor may check your blood pressure. You may need treatment for high blood pressure.

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Common side effects:

- Feeling tired
- Diarrhea, nausea, vomiting, mouth sores, upset stomach, abdominal pain, and constipation. Talk with your doctor about ways to handle these problems.
- The medicine in SUTENT is yellow, so it may make your skin look yellow. Your skin and hair may get lighter.
- Your skin may become dry, get thicker, or crack. You may get blisters or a rash on the palms of your hands and soles of your feet.
- Taste changes
- Loss of appetite
- Bleeding, such as nosebleeds or bleeding from cuts. Call your doctor if you have any swelling or bleeding.
- Swelling
- High blood pressure

There are other side effects. For a more complete list, ask your cancer specialist nurse or doctor.

How should I take SUTENT?

- SUTENT comes in 12.5 mg, 25 mg, and 50 mg capsules you take by mouth. Do not open the capsules.
- Take SUTENT once a day with or without food.
- Take it exactly the way your doctor tells you.
- Do not drink grapefruit juice or eat grapefruit. They may change the amount of SUTENT in your body.
- **Dosing cycle:**
 - Take SUTENT for 4 weeks (28 days) THEN
 - Stop for 2 weeks (14 days)
 - Repeat this cycle as long as your doctor tells you
- Your doctor may check your blood before each dosing cycle.
- If you miss a dose, take it as soon as you remember. Do not take it if it is close to your next dose. Just take the next dose at your regular time. Do not take more than 1 dose of SUTENT at a time. Tell your doctor or nurse about the missed dose.
- Call your doctor right away, if you take too much SUTENT.

How do I store SUTENT?

- Keep SUTENT and all medicines out of the reach of children.
- Store SUTENT at room temperature.

General information about SUTENT

Doctors can prescribe medicines for conditions that are not in this patient information leaflet. Use SUTENT only for what your doctor prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives the most important information about SUTENT. For more information about SUTENT, talk with your doctor or pharmacist. You can visit our website at www.SUTENT.com, or call 1-800-XXX-XXXX.

What is in SUTENT?

Active ingredient: sunitinib malate

Inactive ingredients: mannitol, croscarmellose sodium, povidone (K-25), magnesium stearate **Orange gelatin capsule shell:** titanium dioxide, red iron oxide **Caramel gelatin capsule shell:** yellow iron oxide, black iron oxide **Printing ink:** shellac, propylene glycol, sodium hydroxide, povidone, titanium dioxide

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