

MEDICATION GUIDE

SUTENT (su TENT) (sunitinib malate) capsules

Read the Medication Guide that comes with SUTENT before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about SUTENT, ask your healthcare provider or pharmacist.

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

SUTENT can cause serious liver problems, including death.

- **Tell your healthcare provider right away if you develop any of the following signs and symptoms of liver problems during treatment with SUTENT:**
 - itching,
 - yellow eyes or skin,
 - dark urine, and
 - pain or discomfort in the right upper stomach area.
- Your healthcare provider should do blood tests to check your liver function before you start taking SUTENT and during treatment.

What is SUTENT?

SUTENT is a prescription medicine used to treat people with:

- a rare cancer of the stomach, bowel, or esophagus called GIST (gastrointestinal stromal tumor) and when:
 - the medicine Gleevec® (imatinib mesylate) did not stop the cancer from growing, or
 - you cannot take Gleevec®.
- advanced kidney cancer (advanced renal cell carcinoma or RCC).
- a type of pancreatic cancer known as pancreatic neuroendocrine tumors (pNET), that has progressed and cannot be treated with surgery.

It is not known if SUTENT is safe and effective in children.

What should I tell my healthcare provider before taking SUTENT?

Before taking SUTENT tell your healthcare provider if you:

- 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
- 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

- are pregnant, could be pregnant or plan to become pregnant. SUTENT may harm an unborn baby. You should not become pregnant while taking SUTENT. Tell your healthcare provider right away if you become pregnant while taking SUTENT.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take SUTENT or breastfeed. You should not do both.

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

Tell your healthcare provider about all the medicines you take, including prescription medicines and non-prescription medicines, vitamins, and herbal supplements. Using SUTENT with certain other medicines can cause serious side effects.

You may have an increased risk of severe jaw bone problems (osteonecrosis) if you take SUTENT and a bisphosphonate medicine. Especially tell your healthcare provider if you are taking or have taken Actonel, Aredia, Boniva, Didronel, Fosamax, Reclast, Skelid or Zometa.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Talk with your healthcare provider before starting any new medicines.

How should I take SUTENT?

- Take SUTENT exactly the way your healthcare provider tells you.
- Take SUTENT 1 time each day with or without food.
- If you take SUTENT for GIST or RCC, you will usually take your medicine for 4 weeks (28 days) and then stop for 2 weeks (14 days). This is 1 cycle of treatment. You will repeat this cycle for as long as your healthcare provider tells you to.
- If you take SUTENT for pNET, take it one time each day until your healthcare provider tells you to stop.
- Do not open the SUTENT capsules.
- Do not drink grapefruit juice or eat grapefruit during your treatment with SUTENT. They may cause you to have too much SUTENT in your body.
- Your healthcare provider may do blood tests before each cycle of treatment.
- 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 healthcare provider about any missed dose.
- Call your healthcare provider right away, if you take too much SUTENT.

What are possible side effects of SUTENT?

SUTENT may cause serious side effects including:

- See "[What is the most important information I should know about SUTENT?](#)"
- **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. 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

Your healthcare provider can tell you other symptoms to watch for.

- **Jaw-bone problems (osteonecrosis)**

Severe jaw bone 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 phosphorous levels and low calcium levels in the blood) that can lead to changes in kidney function and acute kidney failure. Your healthcare provider may do blood tests to check you for TLS.
- **Damage to the smallest blood vessels.** Damage to the smallest blood vessels known as thrombotic microangiopathy (TMA) 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 are involved with clotting. TMA may harm organs such as the brain and kidneys. Symptoms of TMA may include fever, fatigue, tiredness, bruising; you may develop 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 on the inside of your mouth. If you develop a rash or these skin symptoms, tell your healthcare provider immediately. Your healthcare provider may tell you to stop taking SUTENT.
- **Hormone problems, including thyroid and adrenal gland problems.** Your healthcare provider may do tests to check your thyroid and adrenal gland function during SUTENT treatment. Tell your healthcare provider if you have any of the following signs and symptoms during treatment with SUTENT:

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| • tiredness that worsens and does not go away | • diarrhea |
| • loss of appetite | • fast heart rate |
| • heat intolerance | • weight gain or weight loss |
| • feeling nervous or agitated, tremors | • feeling depressed |
| • sweating | • irregular menstrual periods or no menstrual periods |
| • nausea or vomiting | • 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. Your healthcare provider should check your blood sugar levels regularly during treatment with SUTENT and may need to adjust the dose of your anti-diabetic medicines. Signs and symptoms of low blood sugar may include:

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|--------------|-------------------|
| • headache | • irritability |
| • drowsiness | • hunger |
| • weakness | • fast heart beat |
| • dizziness | • sweating |

- confusion
- feeling jittery

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 get lighter 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 the possible side effects of SUTENT. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store SUTENT?

- Store SUTENT at room temperature, between 59°F to 86°F (15°C to 30°C).

Keep SUTENT and all medicines out of the reach of children.

General information about SUTENT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 Medication Guide gives the most important information about SUTENT. For more information about SUTENT, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about SUTENT that is written for health professionals.

For more information go to www.SUTENT.com or call 1-877-5-SUTENT.

What are the ingredients 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: titanium dioxide, red iron oxide, yellow iron oxide, black iron oxide **White printing ink:** shellac, propylene glycol, sodium hydroxide, povidone, titanium dioxide

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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