

TAKING SUTENT® (sunitinib malate) capsules

Your doctor has prescribed SUTENT® (sunitinib malate) because he or she believes it is the most appropriate treatment for you. SUTENT may not be appropriate for all patients. SUTENT is available by prescription only.

SUTENT is used to treat advanced kidney cancer (advanced renal cell carcinoma or RCC).

SUTENT is used to treat GIST (gastrointestinal stromal tumor). This is a rare cancer of the stomach, bowel, or esophagus. SUTENT is used to treat GIST when the medicine Gleevec® (imatinib mesylate) does not stop the cancer from growing or when you cannot take Gleevec.

SUTENT is used to treat people with a rare type of pancreatic cancer known as pancreatic neuroendocrine tumors (pNET) that has progressed and cannot be treated with surgery.

Important Safety Information

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
- 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.

Pregnancy and breastfeeding:

- 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
- Do not breastfeed while taking SUTENT

Tell your healthcare provider about all the medicines you take, including prescription medicines and nonprescription 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 (Actonel, Aredia, Boniva, Didronel, Fosamax, Reclast, Skelid, or Zometa). Talk with your healthcare provider before starting any new medicines. 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.

Please see additional Important Safety Information on page 6.

HOW TO TAKE SUTENT

- SUTENT is taken by mouth
 - Your doctor will choose the dose that is most appropriate for you
 - He or she may change or hold your dose from time to time
 - Depending on the dose, you may need to take 1 or more capsules
 - You may take SUTENT with or without food
 - Do not open the SUTENT capsules
- Continue taking SUTENT as directed by your doctor
- Do not drink grapefruit juice or eat grapefruit during your treatment with SUTENT
- Do not take St John's Wort during your treatment with SUTENT
- 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



SUTENT 50 mg



SUTENT 25 mg



SUTENT 12.5 mg

Capsules shown are not actual size.

Gleevec® is a registered trademark of Novartis Pharmaceuticals Corp.

Please see Important Safety Information on page 6.

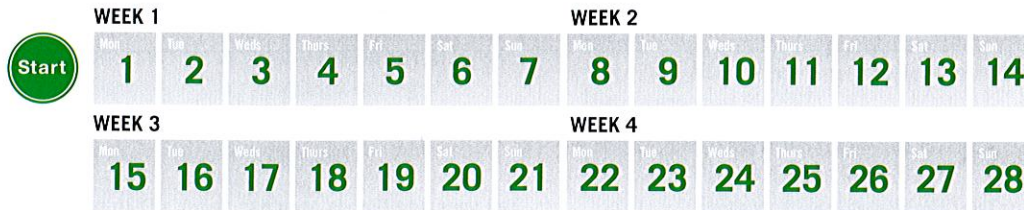
Full Prescribing Information, including Boxed Warning regarding serious liver problems and Medication Guide, is available from your healthcare professional.

The logo for SUTENT capsules, featuring a stylized red and yellow flame-like graphic to the left of the text "SUTENT" in a bold, sans-serif font, with "capsules" in a smaller font above it, and "sunitinib malate" in a smaller font below it.

HOW TO TAKE SUTENT (cont'd)

THE RECOMMENDED DOSING SCHEDULE FOR PATIENTS WITH ADVANCED RCC OR CERTAIN PATIENTS WITH GIST*

TAKE SUTENT EVERY DAY FOR 4 WEEKS (28 DAYS).



DO NOT TAKE SUTENT FOR 2 WEEKS (14 DAYS).



THEN START THE CYCLE AGAIN.

- SUTENT is taken in 6-week cycles
 - Take SUTENT every day for the first 4 weeks (days 1 to 28) of this cycle
 - Stop taking SUTENT for the next 2 weeks (days 29 to 42) to complete the cycle
 - Then begin the next 6-week cycle

*GIST (gastrointestinal stromal tumor) 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.



Recommended dosing schedule for patients with advanced pNET

- Take SUTENT one time each day until your healthcare provider tells you to stop
 - There is no scheduled break in treatment, unless otherwise directed by your doctor

TIPS FOR SIDE EFFECT MANAGEMENT

- During treatment with SUTENT, many patients have side effects. Some can be managed but others are more serious and may not be manageable. In some cases, your doctor may change your dose of SUTENT or stop treatment
- Always talk to your doctor or nurse about any side effects you have as soon as you notice them. Do not wait until they become more serious to tell your doctor or nurse
- Use a journal, which is available for free by enrolling in the In Touch program, to help keep track of your side effects and the tips you use to try to manage them

Please see Important Safety Information on page 6.

2 Full Prescribing Information, including Boxed Warning regarding serious liver problems and Medication Guide, is available from your healthcare professional.

TIPS FOR SIDE EFFECT MANAGEMENT (cont'd)

Always talk to your doctor or nurse about any side effects you have as soon as you notice them. Do not wait until they become more serious.

SIDE EFFECT	TIPS
Fatigue <ul style="list-style-type: none"> • Less desire to do normal activities • Feeling tired, weak, or exhausted 	<ul style="list-style-type: none"> • Take short naps or breaks • Eat well and drink plenty of fluids • Take short walks or do light exercise if you feel up to it • Do things that are relaxing, such as listening to music or reading • Ask your doctor if there are over-the-counter or prescription medications that may help you manage your condition
Diarrhea <ul style="list-style-type: none"> • 3 or more loose or watery stools/bowel movements in 1 day 	<ul style="list-style-type: none"> • It is important for you and your doctor to try to manage diarrhea as soon as it begins • Ask your doctor or nurse if you can be treated with over-the-counter medications • Avoid spicy foods, fatty foods, caffeine, and fruit • Eat only mild foods • Drink water often, but only in small sips
Nausea or vomiting <ul style="list-style-type: none"> • Throwing up or feeling as if you are about to throw up 	<ul style="list-style-type: none"> • It is best to call your doctor or nurse at the first sign of nausea or vomiting <ul style="list-style-type: none"> – This is especially important if these symptoms keep you from taking your oral medications • Your healthcare provider may prescribe a medicine for these symptoms • Eat small meals • Avoid foods that are sweet, fried, or fatty • Drink lots of fluids, but in small amounts • If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again <ul style="list-style-type: none"> – If that stays down, then try soft foods, such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal – Slowly work up to eating solid food – Make sure that you do not eat any food that you are allergic to
Mouth pain <ul style="list-style-type: none"> • Sores or redness in the mouth • A white coating of the tongue • Bleeding gums • Trouble swallowing • Cracks on corner of the mouth 	<ul style="list-style-type: none"> • Avoid hot, spicy, or acidic foods • Eat foods that are soft • Use a straw for drinking liquids • Use an alcohol-free mouthwash, and rinse your mouth often with water • Avoid toothpastes with whiteners (ie, peroxide) and use a soft toothbrush • Ask your doctor if there are over-the-counter or prescription medications that may help you manage your condition
Upset stomach <ul style="list-style-type: none"> • General stomach upset • Indigestion 	<ul style="list-style-type: none"> • Avoid heavy meals, coffee, and alcohol • Reduce your stress with meditation, yoga, or music • Sleep in a more upright position, propped up on a pillow • Ask your doctor if there are over-the-counter or prescription medications that may help you manage your condition
Skin or hair changes <ul style="list-style-type: none"> • Changes in skin or hair color • Rash or dry skin • Blisters • Dryness, thickening, calluses, or cracking of the skin on the palms of your hands and soles of your feet <ul style="list-style-type: none"> – This is called hand-foot syndrome 	<ul style="list-style-type: none"> • In most cases, color change does not require treatment • Wear thick cotton gloves and/or socks • Avoid constrictive footwear and excessive friction • Avoid hot water • Your doctor or nurse may give you specific treatments, which may include lotions, moisturizers, or pain medicines such as ibuprofen or acetaminophen • Yellow eyes or skin may be a sign of serious liver problems. Patients should contact their healthcare provider right away if these conditions develop
Taste changes <ul style="list-style-type: none"> • Foods you usually enjoy taste bland, different, or bad 	<ul style="list-style-type: none"> • Cold or frozen foods may taste better than hot foods • Flavor your food with herbs, seasonings, sugar, or sauces • Keep a clean and healthy mouth by brushing and flossing often
Increased blood pressure <ul style="list-style-type: none"> • SUTENT may cause your blood pressure to rise 	<ul style="list-style-type: none"> • You may receive treatment for high blood pressure (hypertension) • Tell your doctor or nurse if you have high blood pressure or a history of heart disease • If you already have high blood pressure and are receiving treatment, your doctor may change it as needed • Your doctor may also ask you to track your blood pressure regularly in a diary

For more information, including full Prescribing Information and Boxed Warning regarding serious liver problems and Medication Guide, please visit www.sutent.com or contact your healthcare professional.

SIGN UP FOR SUTENT IN TOUCH



A free program to support you during treatment

SUTENT In Touch is a free personalized support program that connects patients and caregivers to relevant information, tips, and tools throughout SUTENT treatment.

By joining In Touch today, you will gain access to many useful resources, including:

- A partnership with a trained oncology certified nurse who is ready to answer your questions and provide helpful information about SUTENT, possible side effects, and your type of cancer
- Personalized mail and e-mail communications, with relevant, timely information about treatment
- E-mails to help keep your SUTENT medication cycles on schedule
- A free treatment journal to track your experiences and to help you make the most of follow-up visits with your healthcare team

Think of the In Touch Call Center as a complement to your treatment team. Our oncology certified nurses are here to provide you with added support. They are even available to check in and call you at key points along your treatment path.

SUTENT In Touch does not replace the advice of your healthcare professional. Be sure to call your doctor or nurse right away if you have side effects or questions about your treatment.

REQUEST YOUR FREE JOURNAL WHEN CALLING TO JOIN IN TOUCH

To enroll, speak to one of our oncology certified nurses by calling **1-877-5-SUTENT (1-877-578-8368)**.

Nurses are available from 9:30 AM to 7 PM ET, Monday through Friday.

When you call, request a free treatment journal. The journal offers more tools and information, including:

- Tips on managing your condition
- Organizational tools for your treatment
- Additional information you may find helpful

For more information, including full Prescribing Information and Boxed Warning regarding serious liver problems and Medication Guide, please visit www.sutent.com or contact your healthcare professional.

Need help accessing your Pfizer oncology medicines?

Pfizer's First Resource program may be able to help. Call 1-877-744-5675 or visit www.FirstResourceProgram.com



First Resource[®]

A Pfizer Helpful Answers Program

How can First Resource[®] help?

Pfizer First Resource is a program designed to help eligible patients obtain the Pfizer medicines they need. It can also provide patients with information about coverage options and alternate funding sources, if needed. Services vary by product and eligibility. First Resource offers:

- **Reimbursement Support Services**—A First Resource counselor will help patients and healthcare professionals understand coverage and reimbursement options. This includes benefit verification, in which the counselor will review patients' benefits to see how they are covered for the medicine they need. The counselor will research and verify benefits, explain coverage options and policies, as well as investigate and explain the prior authorization process
- **Alternate Funding Assistance**—First Resource can help patients find alternate sources of funding if they need them. These may include state pharmaceutical assistance programs, Medicaid, Medicare Part D, low-income subsidies, and charitable foundations
- **Appeals Process Information**—If a claim is underpaid or denied, First Resource will investigate and explain the appeals process
- **Access to Pfizer Medicines**—Patients may be able to get their SUTENT for free through the First Resource patient assistance program. Insured patients experiencing financial hardship may also be able to receive co-pay assistance for SUTENT.[†] A First Resource counselor will help determine patients' eligibility and help patients complete the enrollment process

First Resource is easy to access and use. To find out more, call the counselors at 1-877-744-5675.

[†]Terms and conditions apply. Speak to a First Resource counselor to learn more. Services vary by product and eligibility. First Resource[®] is part of the Pfizer Helpful Answers[®] family of patient assistance programs—a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation[™].

For more information, including full Prescribing Information and Boxed Warning regarding serious liver problems and Medication Guide, please visit www.sutent.com or contact your healthcare professional.

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

Important Safety Information

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
- 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.

Pregnancy and breastfeeding:

- 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
- Do not breastfeed while taking SUTENT

Tell your healthcare provider about all the medicines you take, including prescription medicines and nonprescription 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 (Actonel, Aredia, Boniva, Didronel, Fosamax, Reclast, Skelid, or Zometa). Talk with your healthcare provider before starting any new medicines. 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.

SUTENT may cause serious side effects, including:

- **Serious liver problems, including death**
- **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, 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
- **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:
 - 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.

Full Prescribing Information, including Boxed Warning regarding serious liver problems and Medication Guide, is available from your healthcare professional.

- **Jaw-bone problems (osteonecrosis)**—Severe jaw bone problems may happen. 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
- **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 doctor if you have any of the following signs and symptoms:
 - Tiredness that worsens and does not go away
 - Loss of appetite
 - Nausea or vomiting
 - Diarrhea
 - Fast heart rate
 - Weight gain or weight loss
 - Feeling depressed
 - Heat intolerance
 - Feeling nervous or agitated, tremors
 - Sweating
 - Irregular menstrual periods or no menstrual periods
 - Headache
 - Hair loss

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.

 **SUTENT**^{capsules}
sunitinib malate