



Patient Information Sheet

Sunitinib (marketed as Sutent)

This is a summary of the most important information about Sutent. For details, talk to your healthcare professional.

What Is Sutent?

Sutent is a medicine used to treat adult patients with the following cancers:

- a gastrointestinal stromal tumor after the disease worsened while taking another medicine called imatinib mesylate or when imatinib mesylate cannot be taken.
- advanced renal cell carcinoma. At this time, it is not known whether Sutent will improve symptoms, or help patients with this disease live longer.

Sutent has not been studied in children.

Who Should Not Take Sutent?

Do not take Sutent if you are allergic to Sutent or any of its ingredients.

What Are The Risks?

The following are the major potential risks and side effects of Sutent therapy. However, this list is not complete.

The following are the major possible risks and side effects of Sutent therapy:

- **harm to an unborn baby.** Animal studies show death and birth defects happen in some unborn animal babies. There are no studies of Sutent in pregnant women. Women who can get pregnant should avoid becoming pregnant while taking Sutent.
- **A heart problem called left ventricular dysfunction,** which can cause signs and symptoms of congestive heart failure.
- **stomach and digestive system problems.** Some common stomach and digestive system side effects include:
 - diarrhea
 - nausea
 - mouth sores
 - indigestion

- vomiting
- **an adrenal gland problem called adrenal insufficiency.** This can make it harder for your body to handle the stress of surgery, an infection, or an injury. Tell your healthcare professional right away if you have an injury, an infection, or need surgery. Your adrenal function will have to be monitored closely.
- **skin and hair changes.** Sutent may cause your skin to turn yellow and hair to lose color. Other possible skin side effects include:
 - dryness
 - thickness or cracking
 - blister or rash on the palms of hands and soles of the feet
- **Other common side effects** that may occur with Sutent include:
 - tiredness
 - high blood pressure
 - bleeding
 - swelling
 - mouth pain and irritation
 - taste changes

What Should I Tell My Healthcare Professional?

Before you start taking Sutent, tell your healthcare professional if you:

- are trying to become pregnant, are already pregnant, or are breast-feeding
- have any heart problems
- have an adrenal gland problem

Can Other Medicines Or Food Affect Sutent?

Sutent and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Sutent works or Sutent may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially tell your healthcare professional if you take or eat medicines or foods that may:





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- increase the amount of Sutent in the body, such as:
 - ketoconazole (Nizoral)
 - itraconazole (Sporanox)
 - clarithromycin (Biaxin, Biaxin XL, PreVPac)
 - atazanavir (Reyataz)
 - indinavir (Crixivan)
 - nefazodone (Serzone)
 - nelfinavir (Viracept)
 - ritonavir (Norvir, Kaletra)
 - saquinavir (Fortovase, Invirase)
 - telithromycin (Ketek)
 - voriconazole (VFend)
 - grapefruit
- decrease the amount of Sutent in the body, such as:
 - dexamethasone
 - phenytoin (Dilantin, Phenytek)
 - carbamazepine (Carbatrol, Eptol, Equetro, Tegretol, Tegretol XR, Teril)
 - rifampin (Rifadin, Rifamate, Rifater, Rimactane)
 - rifabutin (Mycobutin)
 - rifapentin (Priftin)
 - phenobarbital
 - St. John's Wort

Sutent and St. John's Wort should not be taken together.

How Should I Take Sutent?

- Sutent is taken by mouth.
- Sutent may be taken with or without food.

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