

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 03/2022

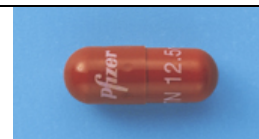
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: SUTENT Capsule 12.5mg

Active ingredient: Sunitinib malate

Dosage form: deep red-brown/deep red-brown capsule, major axis: 14.3 mm, minor axis: 5.3 mm

Print on wrapping: (Face) SUTENT 12.5mg, STN 12.5, (Back) スーテント 12.5mg



Effects of this medicine

This medicine has an anti-tumor effect by suppressing the receptor associated with tumor proliferation and vascularization.

It is usually used to treat imatinib-resistant gastrointestinal stromal tumor, radically unresectable or metastatic renal cell carcinoma and pancreatic neuroendocrine tumors.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reaction (itching, rash, etc.) to any medicine.
- If you have cardiac disorder such as cardiac failure.
- If you are pregnant, possibly pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- For imatinib-resistant gastrointestinal stromal tumor and radically unresectable or metastatic renal cell carcinoma:
In general, for adults, take 4 capsules (50 mg of sunitinib) at a time, once a day for consecutive 4 weeks. Then, discontinue taking this medicine for 2 weeks. This treatment course is repeated. The dosage may be adjusted according to the condition.
- For pancreatic neuroendocrine tumors: In general, for adults, take 3 capsules (37.5 mg of sunitinib) at a time, once a day. The dosage may be adjusted according to the condition. However, the daily dosage is up to 4 capsules (50 mg) once a day.
- In any case, strictly follow the instructions.
- If you miss a dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause dizziness, drowsiness or loss of consciousness. Pay close attention to working at heights or operating dangerous machinery, such as driving a car.
- Avoid taking any food containing St. John's wort (a kind of herb) with this medicine, since it may diminish medicinal effects.
- Avoid taking grapefruit juice with this medicine, since it may intensify the therapeutic effects of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include skin discoloration, hand-foot syndrome (tingling, hot flash, swelling), rash, loss of appetite, diarrhea, nausea, vomiting, mucositis, indigestion, stomatitis, taste abnormality, fatigue and hypertension. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- anemia, fever, bleeding tendency [myelosuppression]
- sore throat, rash, bacterial infection [infections]
- nose bleeding, subcutaneous bleeding, oral bleeding [bleeding]
- breathing difficulty, shortness of breath, edema [cardiac failure, decreased left ventricular ejection fraction]
- sweating, dull, impotent feeling [thyroid dysfunction]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.

•Discard the remainder. Do not store them. Seek advice of your pharmacy or medical institution about proper disposal.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.