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2. Sunitinib

Sunitinib

Generic name: sunitinib [soo-NIT-in-ib]

Brand name: Sutent

Dosage form: oral capsule (12.5 mg; 25 mg; 37.5 mg; 50 mg) **Drug classes:** Multikinase inhibitors, VEGF/VEGFR inhibitors



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What is sunitinib?

Sunitinib is used to treat certain types of advanced or progressive tumors of the stomach, intestines, esophagus, pancreas, or kidneys.

Sunitinib may also be used for purposes not listed in this medication guide.

Sunitinib side effects

Get emergency medical help if you have **signs of an allergic reaction** (hives, difficult breathing, swelling in your face or throat) **or a severe skin reaction** (fever, sore throat, burning in your eyes, skin pain, red or purple skin rash that spreads and causes blistering and peeling).

Sunitinib can cause severe or fatal effects on your liver. Call your doctor if you have loss of appetite, stomach pain (upper right side), tiredness, itching, dark urine, clay-colored stools, or jaundice (yellowing of the skin or eyes).

Sunitinib may also cause life-threatening blood clots in the small blood vessels inside your organs, such as your brain or kidneys. Seek medical help right away if you have symptoms of this condition, such as a fever, tiredness, decreased urination, bruising, or nosebleeds.

Also call your doctor at once if you have:

- pain, redness, numbness, and peeling skin on your hands or feet;
- · easy bruising, unusual bleeding, purple or red spots under your skin;
- painful skin sores, sores in your mouth or on your lips;
- jaw pain or numbness, red or swollen gums, loose teeth, or slow healing after dental work;
- confusion, thinking problems, vision loss, seizure;
- heart problems--swelling, rapid weight gain, fast or pounding heartbeats, fluttering in your chest, shortness of breath, sudden dizziness (like you might pass out);

- increased blood pressure--severe headache, blurred vision, pounding in your neck or ears, dizziness;
- low blood sugar--headache, hunger, weakness, sweating, fast heart rate, feeling jittery;
- signs of bleeding inside your body--change in your mental state, blood in your urine, pain and swelling in your stomach, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds;
- signs of tumor cell breakdown--tiredness, weakness, muscle cramps, nausea, vomiting, diarrhea, fast or slow heart rate, tingling in your hands and feet or around your mouth; or
- symptoms of a thyroid problem--severe and worsening tiredness, depression, fast heart rate, agitation, tremors, feeling nervous, sweating, nausea, vomiting, diarrhea, hair loss, weight changes, irregular menstrual periods.

Common side effects of sunitinib may include:

- indigestion, decreased appetite, stomach pain, nausea, vomiting, diarrhea;
- · feeling weak or tired;
- mouth sores or pain, altered sense of taste;
- blisters or rash on your hands or feet;
- · bruising or bleeding; or
- increased blood pressure.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

1 Sunitinib side effects (more detail)

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Warnings

Sunitinib can cause severe or fatal effects on your liver. You will need frequent blood tests to check your liver function during treatment. Call your doctor if you have any signs of a liver problem, such as right-sided upper stomach pain, itching, dark urine, or jaundice (yellowing of the skin or eyes).

Before taking this medicine

You should not use sunitinib if you are allergic to it.

Tell your doctor if you have ever had:

• kidney problems other than cancer;

- liver disease;
- · heart disease, high blood pressure;
- low blood sugar, or diabetes;
- · bleeding problems;
- long QT syndrome (in you or a family member);
- a thyroid disorder; or
- surgery (or if you plan to have surgery).

sunitinib may cause jaw bone problems (osteonecrosis). The risk is highest in people with cancer, blood cell disorders, pre-existing dental problems, or people treated with steroids, chemotherapy, or radiation. Ask your doctor about your own risk.

Sunitinib can harm an unborn baby or cause birth defects if the mother or the father is using this medicine.

- If you are a woman, do not use sunitinib if you are pregnant. You may need to have a negative pregnancy test before starting this treatment. Use effective birth control to prevent pregnancy while you are using this medicine and for at least 4 weeks after your last dose.
- If you are a man, use effective birth control if your sex partner is able to get pregnant. Keep using birth control for at least 7 weeks after your last dose.
- Tell your doctor right away if a pregnancy occurs while either the mother or the father is using sunitinib.

This medicine may affect fertility (ability to have children) in both men and women. However, it is important to use birth control to prevent pregnancy because sunitinib can harm an unborn baby.

You should not breastfeed while you are using sunitinib and for at least 4 weeks after your last dose.

Sunitinib is not approved for use by anyone younger than 18 years old.

How should I take sunitinib?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

Your blood pressure and liver function may need to be tested at the beginning of each 4-week treatment cycle.

Sunitinib is usually taken once per day. Sunitinib is sometimes taken for 4 weeks followed by 2 weeks off the drug. Your doctor will determine how many complete treatment cycles you need based on your condition.

You may take sunitinib with or without food.

You will need frequent blood and urine tests. Your heart function may also need to be tested with an electrocardiogram (ECG or EKG) on a regular basis, and you may also need frequent dental exams.

If you need surgery or a dental procedure, tell the surgeon or dentist you currently use sunitinib. You may need to stop using the medicine for a short time before and after major surgery.

Store at room temperature away from moisture and heat.

Sunitinib dosing information

Usual Adult Dose for Renal Cell Carcinoma:

50 mg orally once daily on a schedule of 4 weeks on treatment followed by 2 weeks off

Comment: May be taken with or without food.

Uses:

- -For the treatment of advanced renal cell carcinoma (RCC)
- -For the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib.

Usual Adult Dose for Gastrointestinal Stromal Tumor:

50 mg orally once daily on a schedule of 4 weeks on treatment followed by 2 weeks off

Comment: May be taken with or without food.

Uses:

- -For the treatment of advanced renal cell carcinoma (RCC)
- -For the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib.

Usual Adult Dose for Pancreatic Cancer:

37.5 mg orally once daily

Comments:

-To be taken continuously without a scheduled off-treatment period; may be taken with or without food.

Use: For the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

Detailed Sunitinib dosage information

What happens if I miss a dose?

Use the medicine as soon as you can, but skip the missed dose if you are more than 12 hours late for the dose. **Do not** use two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking sunitinib?

Grapefruit may interact with sunitinib and lead to unwanted side effects. Avoid the use of grapefruit products.

What other drugs will affect sunitinib?

Sunitinib can cause a serious heart problem. Your risk may be higher if you also use certain other medicines for infections, asthma, heart problems, high blood pressure, depression, mental illness, cancer, malaria, or HIV.

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Tell your doctor about all your other medicines, especially:

• osteoporosis medicine.

This list is not complete. Other drugs may affect sunitinib, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Sunitinib drug interactions (more detail)

Does sunitinib interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

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DRUG STATUS

Availability Rx Prescription only Pregnancy & Lactation Risk data available CSA Schedule* N/A Not a controlled drug Approval History

Drug history at FDA

User Reviews & Ratings

7.3 / 10

35 Reviews

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Sunitinib Malate 12.5 mg (TEVA 8199 TEVA 8199)





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