

Patient Information Leaflet

Sunitinib - SUTENT®

What is SUTENT®

Medicine Name	Description
Sunitinib	12.5 mg gelatin capsule: red 25 mg gelatin capsule: orange and red 50 mg gelatin capsule: orange

How should you take your medicine?

Your doctor has determined your medicine dosage.

......(indicate whether or not to take

Swallow whole with a glass of water, without opening or diluting the capsules. At a set time, with or without meals.

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

Dosage – therapy regimen

Once a day, at a set time, with or without meals		S			101			101	
With no gaps OR from D1 through D28, every 6 weeks	D1	D2	D3	D4	D 5	D 6	O 7	•••	D28
			D1	D28	D29	•••	D42		

How to get the medicine supply?

This medicine is available in local pharmacies.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

What else do you need to know?

Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts, liver, pancreas, and thyroid gland function; albumin urine test), as well as clinical condition monitoring (blood pressure, ECG, cardiac scintigraphy).

Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).

Interactions with other medications and/or food

The occurrence of interactions between SUTENT® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.

Example: While taking SUTENT®, it is necessary to avoid using Saint John's wort, grapefruit juice, ginkgo biloba, bitter orange, butcher's broom, licorice, and yohimbine.

What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.



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SIDE EFFECTS	
Most common ones	Digestive problems: loss of appetite, taste perception disorder, diarrhea, nausea, inflammations inside the mouth (ulcers), acid reflux, vomiting Cardiac problems, including hypertension Skin problems: skin and/or hair discoloration, hand-foot syndrome, skin rash, dryness Abnormal lab results: impaired thyroid gland function (hypothyroidism), low multinuclear neutrophil count (neutropenia), low platelet count (thrombocytopenia), low hemoglobin level (anemia),hypoglycemia Pain: hands, feet, joints, headaches Eye problems: tears, swelling Infections Others: fatigue, sleep disorder, dizziness, bleedings / hemorrhages
Some patients require special attention	Patients with diabetes (hypoglycemia)
WHEN TO ALERT THE MEDIC	CAL TEAM?
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	> Significant and/or rapid weight loss > Very frequent diarrhea, bowel movement over 4 times a day > Mouth pain or ulcers that prevent normal eating > Severe abdominal pain > Inability to drink for 24 hours and/or eat for about 48 hours Hypertension symptoms Headaches, buzzing in the ears, and/or dizziness Blood pressure increase Symptoms suggestive of hemorrhage Blood in stool or in vomit Hematomas (bruises), nose bleedings Symptoms suggestive of infection Temperature > 38.5 °C Cough, throat pain, pain on urination, diarrhea with fever Pain that prevents you from doing your normal activities > Headaches > Joint pain Symptoms suggestive of cardiac problems Shortness of breath, high palpitations, chest pain or tightness Hypoglycemia symptoms > Dizziness, nausea, vision problems, muscle weakness Symptoms suggestive of phlebitis > Red, warm, and painful calf
HOW TO PREVENT SIDE EFF	ECTS?
Blood pressure control	Elevated blood pressure needs to be corrected. Taking arterial pressure regularly is recommended. Pharmacists can help you take your blood pressure. You can also ask to do it by yourself using an automatic blood pressure monitor.
Weight	Regularly check your weight in case of digestive problems.
Oral hygiene	Use a soft toothbrush; use oral rinses containing baking soda. Avoid oral rinses that contain menthol or alcohol.
Skin care	On hands and feet: Apply moisturizing cream or milk and/or healing cream on hands and feet (without rubbing hard). Avoid exposing hands and feet to heat (hot water). Avoid activities that cause rubbing or injury. Avoid wearing overly tight clothing, socks, or shoes Body: Opt for soft soap and moisturizer, pat skin dry. Avoid using any irritating products



Fatigue

For sun protection, use broad spectrum sunscreen and avoid sun exposure.

Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking,

Avoid using any irritating products.

work in the garden, swimming, biking, sports... Alternate periods of activity and rest.

Bleeding / hemorrhages	Avoid taking anti-inflammatory drugs (ibuprofen, aspirin) Notify your doctor: > if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed
lafa-da-	> about surgical or dental intervention.
Infection	A flu and pneumococcal infection vaccine might be recommended for you: it will protect you.
HOW TO ADAPT YOUR DIET?	?
Loss of appetite	Opt for a higher calorie diet and "pleasure diet".
Taste perception disorders	Opt for several small meals of warm and cold food per day. Avoid using metal kitchen utensils.
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas. Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol. Drink more water.
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes. Limit consumption of fatty, fried, and spicy foods.
Inflammation inside mouth (ulcers)	Avoid sour, sticky, or very salty foods.
Acid reflux	Avoid using alcohol, tobacco, coffee, and large, fatty meals. Opt for split nutrition.