GISTMED

Sunitinib Hard Capsules (12.5 mg, 25mg, 50mg)

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What SUNITINIB is used for

SUNITINIB is used to treat adults with the following types of cancer:

Gastrointestinal stromal tumour (GIST), a type of cancer of the stomach and bowel. After disease progression on or, where imatinib (another anticancer medicine) no longer works or you cannot take imatinib.

Advanced renal cell carcinoma, a type of kidney cancer that has spread to other parts of the body.

Pancreatic neuroendocrine tumours (pNET), tumours of the hormone-producing cells in the pancreas that have progressed or cannot be removed with surgery.

How SUNITINIB works

SUNITINIB is used to treat cancer by preventing the activity of a special group of proteins which are known to be involved in the growth and spread of cancer cells.

Before you use SUNITINIB

- *When you must not use it*

Do not take SUNITINIB

If you are allergic to SUNITINIB or any of the other ingredients of SUNITINIB.

Pregnancy and lactation

There are no studies in pregnant women using SUNITINIB. If you are pregnant or think you may be pregnant, tell your doctor. SUNITINIB is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risk of taking SUNITINIB during pregnancy. If you might get pregnant, you should use reliable method of contraception during treatment with SUNITINIB.

If you are breastfeeding, tell your doctor. Do not breastfeed during treatment with SUNITINIB.

- *Before you start to use it*

Talk to your doctor before taking SUNITINIB:

- If you have or had liver and kidney problems (protein in your urine), your doctor should perform a liver function test and urine analysis before initiation of SUNITINIB;
- If you have heart problems or an abnormality of your heart rhythm known as prolonged QT interval, your doctor should perform a test of your heart's ejection fraction (volume of blood in percentage that is pumped out of your heart per heart beat) prior to initiating SUNITINIB;
- If you are diabetic or have a history of blood sugar problems, your doctor will check your blood sugar levels regularly to determine if your anti-diabetic medications need to be adjusted to avoid low blood sugar levels (hypoglycemia);
- If you are receiving or have received a medicine called intravenous bisphosphonates;
- If you had stomach cancer, you may be at increased risk of getting holes in your gastrointestinal tract when taking SUNITINIB;
- If you have or had a history of hypertension which may promote the enlarging of artery (aneurysm) or a tear in an artery (artery dissection).

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may increase or decrease the concentration of SUNITINIB in your blood. You should inform your doctor if you are taking medicines and supplements containing the below:

- Ketoconazole, Itraconazole (used to treat fungal infections);
- Erythromycin, Clarithromycin, Rifampin (used to treat infections);
- Ritonavir (used to treat Human Immunodeficiency virus (HIV));
- Dexamethasone (a corticosteroid used for various conditions);
- Phenytoin, Carbamazepine, Phenobarbital (used to treat epilepsy and other nerve conditions);
- Herbal preparations containing St. John's Wort (*Hypericum perforatum*) (used to treat depression and anxiety);
- Grapefruit juice.

How to use SUNITINIB

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will prescribe a dose that is right for you, depending on the type of cancer you are being treated for. If you are being treated for GIST or advanced renal cell carcinoma, the usual dose is 50 mg once daily taken for 28 days (4 weeks), followed by 14 days (2 weeks) of rest (no medicine), in 6-week cycles. If you are being treated for pNET, the usual dose is 37.5 mg once daily without a rest period.

Your doctor will determine the appropriate dose you need to take as well as if and when you need to stop treatment with SUNITINIB.

- *When to use it*

Use as directed by your doctor or pharmacist.

SUNITINIB may be taken with or without food.

- *How long to use it*

Continue taking SUNITINIB for as long as your doctor recommends.

- *If you forget to use it*

If you missed a dose, do not take an additional dose. You should take the usual prescribed dose on the following day. Consult your doctor or pharmacist if you are unsure about what you should do.
Do not take a double dose to make up for a forgotten dose.

- *If you use too much* (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking SUNITINIB.
Tell your doctor immediately:

- if you become pregnant while taking SUNITINIB;
- if you have a severe skin reaction (skin rash, sometimes with blisters);
- if you have problems with excessive bleeding (for example, nose bleeds, coughing up blood, blood in your stools or urine). SUNITINIB may increase your risk of bleeding as it may lead to changes in number of certain cells in your blood, which affects the ability of your blood to clot. It may also reduce your red blood cells. Your doctor will perform routine physical examination and blood test to determine your complete blood count;
- if you have gastrointestinal problems (including sore mouth, indigestion, diarrhea or nausea), your doctor may provide anti-vomiting or anti-diarrheal tablets to control these symptoms;
- if you have pain in the area of the stomach (upper abdomen), nausea, vomiting and fever. These may be signs of inflammation of the pancreas (pancreatitis) or signs of inflammation of the gall bladder (cholecystitis), at which your doctor may decide to stop SUNITINIB;
- if you experience a sudden increase in your blood pressure, your doctor may need to treat your blood pressure separately. If your blood pressure is severely high, your doctor may consider temporarily stopping SUNITINIB;
- if you experience signs of thyroid under activity or thyroid over activity, your doctor may need to treat your thyroid separately. Your doctor would usually perform a thyroid function test before you start treatment;
- if you will be undergoing a major surgical procedure, or have had a surgery recently. SUNITINIB can affect the way your wound heals. Your doctor may need to temporarily interrupt your SUNITINIB treatment until you have recovered from your surgery; if you experience seizures tell your doctor; if you experience pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs and symptoms of bone damage in the jaw (osteonecrosis);
- if you need to undergo an invasive dental treatment or dental surgery, your doctor should send you for a dental examination and ensure you have appropriate preventative dentistry before treatment with SUNITINIB.
- if you have symptoms such as lack of energy, confusion, sleepiness, unconsciousness/coma, your doctor will measure your ammonia level and determine appropriate treatment because these may be signs of brain toxicity caused by high blood levels of ammonia (hyperammonaemic encephalopathy).

- *Things you must not do*

Do not stop taking SUNITINIB unless advised by your doctor.

Do not take any new medicines without consulting your doctor. Do not give SUNITINIB to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

SUNITINIB has minor influence on the ability to drive and use machines. You may experience dizziness during treatment with SUNITINIB.

Side Effects

Like all medicines, SUNITINIB can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. The most important serious side effects associated with SUNITINIB treatment of solid tumour were blood clot in the lung (causing chest pain and breathlessness), reduction in the number of platelets (a type of blood cell), fever with low neutrophil count (a type of white blood cell), tumor bleeding, and high blood pressure.

Very common side effects reported are as follows:

- Infections associated with fever and chills;
- Decreased activity of the thyroid gland (hypothyroidism);
- Decreased appetite;
- Sleeplessness;
- Breathlessness;
- Altered taste;
- Headache;
- Bleeding from nose;
- Loose stools, nausea, vomiting, hard stools;
- Stomach pain, mouth ulcers;
- Indigestion;
- Rash, dry skin, skin discoloration, change in hair color, hand-foot disease causing redness, swelling and pain; Joint pain, pain in arms and legs;
- Fatigue;
- Inflammation of mucosa (lips and mouth);
- Swelling;
- Fever;

Common side effects reported are as follows:
- Low blood sugar;
- Dehydration;
- Depression;
- Dizziness;
- Tingling and prickling sensations;
- Swelling around the eyes, eyelid swelling, increased tears;
- Reduced blood flow to the heart;
- Decreased capacity of heart to pump out blood;
- A blood clot in a deep vein, usually in the legs;
- Build-up of fluid between the tissues that line the lungs and the chest;
- Blood in the phlegm;
- Sore throat;
- Excessive gas in the stomach or intestine;
- Oral pain, bleeding in the stomach or intestine; inflammation of the oesophagus, heartburn, burning tongue, dry mouth, distended tummy, gum bleeding;
- Skin peeling, hair loss, redness of skin, itching, skin lesions, skin reaction, nail disorders, blister formation;
- Muscle pain;
- Kidney failure, abnormally colored urine, loss of protein in the urine;
- Flu-like symptoms (chills, fever, sore throat, swollen glands), reduction in the number of platelets, red blood cells, white blood cells (e.g. lymphocytes);
- Abnormal blood tests including increased pancreatic enzymes, increased uric acid in the blood and increased in a type of tissue enzyme called creatinine phosphokinase;
- Weight loss;
- Loss of taste;

These are not all the side effects for SUNITINIB. If you experience any of these side effects that would not go away, tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my
[Consumers➞Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of SUNITINIB
- *Storage*

Store below 30°C.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Information
- *What it looks like*

12.5 mg capsules

Hard gelatin capsule with orange opaque cap and orange opaque body imprinted with white ink "SML" on the cap and "20" on the body containing orange granular powder. Each capsule contains SUNITINIB Malate equivalent to 12.5 mg of SUNITINIB.

25 mg capsules

Hard gelatin capsule with caramel opaque cap and orange opaque body imprinted with white ink "SML" on the cap and "21" on the body containing orange granular powder. Each capsule contains SUNITINIB Malate equivalent to 25 mg of SUNITINIB.

50 mg capsules

Hard gelatin capsule with caramel opaque cap and caramel opaque body imprinted with white ink "SML" on the cap and "23" on the body containing orange granular powder. Each capsule contains SUNITINIB Malate equivalent to 50 mg of SUNITINIB.

- *Ingredients*

- Active ingredient
Sunitinib malate

- Inactive ingredients
Mannitol, Croscarmellose Sodium, Povidone(K-25), Magnesium Stearate, Purified water.

Capsule shell:

12.5 mg capsules

Empty Hard Gelatin Capsules (Size 4), (Orange opaque cap & Orange opaque body).

25 mg capsules

Empty Hard Gelatin Capsules (Size 3), (Caramel opaque cap and Orange opaque body).

50 mg capsules

Empty Hard Gelatin Capsules (Size 2), (Caramel opaque cap and Caramel opaque body).

- *MAL number(s):*

GISTMED 50- Sunitinib Hard Capsules 50 mg - MAL25086009AZ
GISTMED 25- Sunitinib Hard Capsules 25 mg - MAL25086008AZ
GISTMED 12.5- Sunitinib Hard Capsules 12.5 mg - MAL25086007AZ

Manufacturer
Shilpa Medicare Limited (Unit IV), Plot No's S-20 to S-26, Pharma SEZ, TSIIC, Green Industrial Park, Polepally (V), Jadcherla (M), Mahabubnagar (Dt), 509301 Telangana, India.

Product Registration Holder
Unimed Sdn. Bhd.,
53, Jalan Tembaga SD5/2B, Bandar Sri Damansara,
52200 Kuala Lumpur, Malaysia.

Serial Number:
NPRA (R2) 23/216

Date of revision
04/05/2026