PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SUTENT® 12,5 mg capsules

SUTENT® 25 mg capsules

SUTENT® 50 mg capsules

Sunitinib

Contains sugar

Each SUTENT 12,5 mg capsule contains 80,0 mg mannitol

Each SUTENT 25 mg capsule contains 39,663 mg mannitol

Each SUTENT 50 mg capsule contains 79,326 mg mannitol

Read all of this leaflet carefully before you start taking SUTENT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SUTENT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SUTENT is and what it is used for
2. What you need to know before you take SUTENT
3. How to take SUTENT
4. Possible side effects
5. How to store SUTENT
6. Contents of the pack and other information

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1. What SUTENT is and what it is used for

SUTENT is used in the treatment of some cancers:

- Gastrointestinal stromal tumour (GIST)
- Metastatic renal cell carcinoma (MRCC)
- Pancreatic neuroendocrine tumours (pNET)

2. What you need to know before you take SUTENT

Do not take SUTENT:

- if you are hypersensitive (allergic) to sunitinib or any of the other ingredients of SUTENT (listed in section 6)
- if you are pregnant or are planning to have a baby
- if you are breastfeeding your baby (see Pregnancy and breastfeeding)

Warnings and precautions

Take special care with SUTENT:

Some people will need special care from their doctors when they are taking SUTENT. Make sure that your doctor knows before you start taking SUTENT:

- if you have or have had a serious skin reaction
- if you have or have had blood disease, bleeding problems or bruising
- if you have or have had pancreatic disorders
- if you have or have had liver problems. Tell your doctor if you develop any of the following signs and symptoms of liver problems during SUTENT treatment: itching, yellow eyes or skin, dark urine, and pain or discomfort in the right upper stomach area
- if you have heart problems or high blood pressure. You should have your blood pressure checked regularly.
- if you have an abnormality of your heart trace (shown in an ECG) known as prolonged QT interval

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- if you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall
- if you have an under-active thyroid gland before starting treatment with SUTENT, or if your thyroid gland becomes less active during treatment
- if you have or have had seizures or fits
- if you are going to have surgery or if you had an operation recently, as SUTENT may affect the way your wounds heal. You will usually be taken off SUTENT if you are having an operation. Your doctor will decide when to start SUTENT again.
- You may be advised to have a dental check-up before you start treatment with SUTENT.
  - if you have or had 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, tell your doctor and dentist immediately.
  - if you need to undergo an invasive dental treatment or dental surgery, tell your dentist that you are being treated with SUTENT, and in particular when you are also receiving or have received IV bisphosphonates (medicines to treat a bone disease referred to as osteoporosis).
- if you have or have had problems with blood clots in your veins and/or arteries
- if you have or have had kidney problems
- if you have diabetes
- if you have previously had or have recently tested positive for a hepatitis B infection. Tell your doctor if you experience fever, chills, weakness, confusion, vomiting, itching, yellow eyes or skin, dark urine, pain or discomfort in the right upper stomach area
- if you experience trouble walking, speaking, and understanding, as well as paralysis or numbness of the face, arm, or leg

Other medicines and SUTENT

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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Some medicines can affect the levels of SUTENT in your body. You should inform your doctor if you are taking any of the following medicines:

- ketoconazole, itraconazole - used to treat fungal infections
- erythromycin, clarithromycin, rifampicin - medicines used to treat infections and tuberculosis
- ritonavir - medicine used to treat HIV
- dexamethasone - a corticosteroid used for various conditions
- phenytoin, carbamazepine, phenobarbitone - treatments for epilepsy and other conditions
- herbal preparations containing St. John's Wort (*Hypericum perforatum*) – used for depression and anxiety

SUTENT with food and drink

You should avoid drinking grapefruit juice while on treatment with SUTENT.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

SUTENT could harm an unborn baby. Do not take this medicine during pregnancy.

Talk to your doctor before taking SUTENT if you might become pregnant. Use a reliable method of contraception while you are taking SUTENT and for 4 weeks after the last dose of SUTENT to prevent pregnancy.

Do not breastfeed during treatment with SUTENT.

Driving and using machines

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If you feel dizzy or unusually tired after taking SUTENT, do not drive or use machinery until you are feeling normal again.

It is not always possible to predict to what extent SUTENT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SUTENT affects them.

SUTENT contains mannitol

SUTENT capsules contain mannitol (type of sugar) and may have a laxative effect.

3. How to take SUTENT

Do not share medicines prescribed for you with any other person.

Always take SUTENT exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you are being treated for GIST or renal cancer, the usual dose is 50 mg once daily taken for 28 days (4 weeks), followed by 14 days (2 weeks) of rest (no medicine), given as a 6-weeks cycle.

If you are being treated for pNET, the usual dose is 37,5 mg once daily without a rest period.

SUTENT may be taken with or without food.

Your doctor will tell you how long your treatment with SUTENT will last. Do not stop your treatment early. If you have the impression that the effect of SUTENT is too strong or too weak, tell your doctor or pharmacist.

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If you take more SUTENT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take SUTENT

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SUTENT can have side effects.

Not all side effects reported for SUTENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SUTENT, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Hypersensitivity reactions. Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to SUTENT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you experience any of the following:

- Heart problems. Tell your doctor if you feel very tired, are short of breath, or have swollen feet and ankles. These may be symptoms of heart problems that may include heart failure and heart muscle problems (cardiomyopathy).

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- Lung or breathing problems. Tell your doctor if you develop cough, chest pain, sudden onset of shortness of breath or coughing up blood. These may be symptoms of a condition called pulmonary embolism that occurs when blood clots travel to your lungs.
- Kidney disorders. Tell your doctor if you experience a change in the frequency or absence of urination, which may be symptoms of kidney failure.
- Bleeding. Tell your doctor right away if you have a serious bleeding problem or any of these symptoms during treatment with SUTENT:
    - painful, swollen stomach (abdomen), vomiting blood, black, sticky stools, bloody urine, headache, changes in your mental status, coughing up of blood or bloody sputum from the lungs or airway

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infections
- Reduction in the number of platelets, red blood cells and/or white blood cells
- Decreased activity of thyroid gland (hypothyroidism)
- Loss/decrease of appetite, dehydration, weight loss
- Decreased blood sugar levels
- Difficulty in falling asleep
- Depression
- Taste disturbances
- Headache
- Dizziness
- Swelling around the eyes, swelling of the eyelid
- Excessive tear flow

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- Heart disease
- Decrease in the amount of blood pumped by the heart
- High blood pressure
- Shortness of breath
- Formation of blood clots (thrombi) in the deep veins, usually in the legs
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).
- Nose bleeds
- Throat pain
- Coughing up of blood
- Blood clot in the lungs
- Accumulation of fluid in the area between the two layers of the thin membrane that covers the lung. You may experience shortness of breath and chest pain
- Diarrhoea, nausea, vomiting, abdominal pain/swelling, constipation, upset stomach, excessive gas in the stomach or intestine, indigestion, acid heartburn, acid reflux
- Mouth sores/swelling, mouth pain/irritation, burning or painful sensation in the tongue, bleeding gums, dry mouth
- Bleeding in the stomach
- Inflammation of food pipe (oesophagus)
- Tingling, tickling, pricking, numbness or burning of the skin, rash on the palms of the hands and soles of the feet, yellow skin/skin discoloration, skin rash, redness of the skin or mucous membranes, dry, itching, flaking, blisters bumps, sores or painful ulcers on the skin, abnormal sensation of the skin, inflammation of the skin
- Hair colour change, hair loss
- Nail disorder
- Pain in arms and legs, joint pain, muscle pain
- Kidney failure, abnormally coloured urine, excess protein in the urine

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- Extreme tiredness, loss of strength
- Swelling caused by fluid under the skin
- Mucosal inflammation, fever, chills, flu-like illness
- Abnormal blood tests including increased pancreatic enzymes
- Increased uric acid in the blood

Less frequent side effects:

- Blood clots in the blood vessels
- Inappropriate and excessive allergic reaction
- Overproduction of thyroid hormones
- Inflammation of the thyroid gland
- Metabolic complications
- Bleeding in the brain
- Abnormal changes in the brain that can cause a collection of symptoms including headache, confusion, seizures, and vision loss
- Blood clot in the brain
- Heart failure, heart attack or stroke
- Changes in the electrical activity or abnormal rhythm of your heart
- Diseases of the heart muscle
- Rapid or irregular heartbeat
- Tumour bleeding
- Inflammation of the pancreas
- Gastrointestinal perforation (ruptured bowel, hole in the stomach)
- Inflammation (swelling and redness) of the gallbladder with or without associated gallstones
- Liver failure
- Reactivation of hepatitis B infection

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- 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). Tell your doctor and dentist immediately if you experience any of them.
- Abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
- Disease of the muscles (myopathy)
- Kidney failure, kidney damage
- Urinary tract bleeding
- Increased muscle enzyme blood levels
- Increased levels of thyroid stimulation hormone in your blood

Other side effects

Lack of energy, confusion, sleepiness, unconsciousness/coma – these symptoms may be signs of brain toxicity caused by high blood levels of ammonia (hyperammonaemic encephalopathy).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor/ pharmacist/ nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SUTENT.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store SUTENT

Store all medicines out of reach of children.

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Store at or below 30 ºC.

Store in the original packaging and do not take the capsules after the expiry date shown on the container.

If your capsules are out of date, take them to your pharmacist who will get rid of them safely.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SUTENT contains

Each capsule contains 12,5 mg, 25 mg or 50 mg of sunitinib (as the malate salt).

The other ingredients are croscarmellose sodium, magnesium stearate, mannitol and povidone.

The capsule shell is composed of black iron oxide (CI 77499) (25 mg and 50 mg), gelatin, red iron oxide (CI 77491) (12,5 mg, 25 mg and 50 mg), titanium dioxide (CI 77891) and yellow iron oxide (CI 77492) (25 mg and 50 mg). The imprinting ink contains povidone, propylene glycol, shellac, sodium hydroxide, and titanium dioxide (CI 77891).

What SUTENT looks like and contents of the pack

SUTENT 12,5 mg capsules are hard gelatin, with an orange cap and orange body, printed with white ink “Pfizer” on the cap and “STN 12,5 mg” on the body. The capsules contain yellow to orange granules.
SUTENT 25 mg capsules are hard gelatin, with a caramel cap and orange body, printed with white ink “Pfizer” on the cap and “STN 25 mg” on the body. The capsules contain yellow to orange granules.
SUTENT 50 mg capsules are hard gelatin, with a caramel cap and caramel body, printed with white ink “Pfizer” on the cap and “STN 50 mg” on the body. The capsules contain yellow to orange granules.

SUTENT is supplied in opaque white high-density polyethylene bottles with a white child resistant polypropylene closure and a heat induction seal liner containing 28 or 30 hard gelatin capsules.

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SUTENT capsules are available in blister strips of 28 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

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