PART III: CONSUMER INFORMATION

Pr SUTENT®
(sunitinib)

This leaflet is part III of a three-part "Product Monograph" published when SUTENT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SUTENT. Contact a member of your healthcare team if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SUTENT is an oral medicinal product used in the treatment of 3 types of cancer:

1. gastrointestinal stromal tumour (GIST), a cancer of the stomach and bowels. GIST arises from uncontrolled cell growth of the supporting tissues of these organs.

2. kidney cancer that has spread to other parts of your body.

3. Pancreatic neuroendocrine tumour (pancreatic NET). This is a rare cancer of the endocrine pancreas. SUTENT is used when the cancer cannot be treated with surgery.

What it does:

SUTENT specifically targets the activity of certain enzymes called tyrosine kinases that play a major role in transmitting the chemical signals required for critical cellular processes. SUTENT prevents the growth of blood vessels from surrounding tissue to a solid tumour, and prevents the proliferation of cancer cells.

When it should not be used:

Do not take SUTENT:

- If you are allergic (hypersensitive) to sunitinib or any of the other ingredients of SUTENT, listed under "**What the important nonmedicinal ingredients are:"**
- If you are pregnant.

What the medicinal ingredient is:

The active ingredient is sunitinib (as malate salt).

What the important nonmedicinal ingredients are:

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

The orange capsule shells contain gelatin, red iron oxide and titanium dioxide. The caramel capsule shells also contain black iron oxide and yellow iron oxide. The imprinting ink contains povidone, propylene glycol, shellac, sodium hydroxide and titanium dioxide.

The yellow capsule shells contain titanium dioxide, yellow iron oxide, and gelatin. The imprinting ink for the yellow shells contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, potassium hydroxide, and black iron oxide.

What dosage forms it comes in:

SUTENT is available as hard gelatin capsules containing 12.5 mg; 25 mg; 37.5[§] mg or 50 mg of sunitinib. SUTENT is available in bottles of 28 or 30[§] capsules and in blister[§] strips boxed as 28 capsules (combination of 4 strips of 7 capsules).

SUTENT 12.5-mg capsules: Capsules are supplied with orange cap and orange body, printed with white ink "Pfizer" on the cap, "STN 12.5 mg" on the body.

SUTENT 25-mg capsules: Capsules are supplied with caramel cap and orange body, printed with white ink "Pfizer" on the cap, "STN 25 mg" on the body.

SUTENT 37.5[§]-mg capsules: Capsules are supplied with standard yellow cap and standard yellow body, printed with black ink "Pfizer" on the cap, "STN 37.5 mg" on the body.

SUTENT 50-mg capsules: Capsules are supplied with caramel cap and caramel body, printed with white ink "Pfizer" on the cap, "STN 50 mg" on the body.

[§] *not commercially available in Canada*

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Patients receiving SUTENT should be monitored by a doctor with experience in cancer medicines.

Serious side effects have been reported with SUTENT include:

- **Rare cases of Tumour Bleeding.**
- **Decreases in the amount of blood pumped by your heart (Left Ventricular Dysfunction), including fatal cases.**
- **High blood pressure.**
- **QT prolongation (SUTENT may cause an irregular heartbeat), including fatal cases.**
- **Heart muscle disorders (cardiomyopathy), including fatal cases**
- **Blood clots in the lung, including fatal cases**
- **Damage to the smallest blood vessels [Thrombotic microangiopathy (TMA)], including fatal cases**
- **Blood clots in the artery which could lead to stroke or heart attack, including fatal cases**
- **Muscle disorders (myopathy and/or rhabdomyolysis), including fatal cases.**
- **Kidney failure, including fatal cases.**
- **Serious liver problems, including death, have been reported.**
- **Reversible Posterior Leukoencephalopathy Syndrome, including fatal cases**
- **Buildup of fluid between layers of tissue in the lungs and the chest cavity (pleural effusion), including fatal cases**

SUTENT has not been studied in patients with severe liver problems.

SUTENT has an effect on the electrical activity of the heart. This effect can be measured as a change in the electrocardiogram (ECG). This effect can lead to heart rhythm disturbances. These heart rhythm disturbances may be more likely in patients with risk factors, such as heart disease, or in the presence of certain interacting drugs. If you feel dizzy, weak, faint, or light-headed, and your pulse is irregular or unusually low or high, you should stop taking SUTENT and seek immediate medical attention. It is important to follow the instructions of your doctor with regard to dosing or any special tests.

Cases of Tumour Lysis Syndrome [TLS] have been reported during the use of SUTENT. TLS is a metabolic condition that results from dying cancer cells and involves changes in blood chemistry that can lead to kidney failure and abnormal heart rhythm, which may be fatal. Tell your doctor immediately if you have palpitations/irregular heartbeats; vomiting; fatigue/weakness; difficulty concentrating/trouble thinking; swelling, numbness or tingling in hands, face or feet; back pain; muscle cramps; fainting or trouble breathing.

Cases of the following have been reported with the use of SUTENT:

- Life-threatening infection of the soft tissue including the ano-genital area (necrotizing fasciitis)
- Painful skin ulcers (pyoderma gangrenosum)
- Cholecystitis (inflammation of the gall bladder), in some cases fatal
- Severe and sometimes life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme)
- Damage to the smallest blood vessels (TMA), including deaths.

Tell your doctor before taking SUTENT, if any of the following apply to you now or even in the past:

- If you have thyroid problems
- If you have an adrenal gland problem
- If you have or have had muscle aches or weakness
- If you have bleeding problems
- If you have or had liver or kidney problems.
- If you have high blood pressure and its complications, including separation of the layers of the arterial wall (Artery Dissection).
- If you are pregnant or think you may be. SUTENT is not to be used during pregnancy. Women who might get pregnant must use effective contraception during treatment with SUTENT.
- If you are breast-feeding.
- If you have had recent surgery, injury or a severe infection. SUTENT can affect the way your wound heals.
- If you have a heart condition.
- If you have had a stroke.
- If you have a history of fainting spells.
- have or have 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
- need to undergo an invasive dental treatment or dental surgery, in particular if you are also receiving or have received i.v. bisphosphonates (a bone builder that may have been given for another medical condition)
- If you have a family history of sudden cardiac death at age less than 50 years.
- If you are male and plan to father a child.

Use in children (under 18 years):
Experience with SUTENT in children is limited. Therefore SUTENT is not recommended for use in children.

Contraception
SUTENT may cause harm to an unborn child. Female patients who might get pregnant must use effective contraception during treatment with SUTENT. Since SUTENT may present in the semen, male patients who are not surgically sterile must agree to use effective contraception during treatment with SUTENT to prevent pregnancy in female partners.

If pregnancy is suspected during treatment with SUTENT, inform your doctor immediately.

Driving and using machines:
If you experience (feel) dizziness, do not drive or use machinery.

INTERACTIONS WITH THIS MEDICATION

Taking other medicines:
Tell your doctor if you are taking other drugs, including non-prescription and natural health products, because they may speed up or slow down the breakdown of SUTENT. This may lead to an increase in SUTENT drug levels, which may lead to an increase in the side effects of SUTENT. For example:

- Antifungals (such as ketoconazole, fluconazole)
- Calcium channel blockers (such as diltiazem, verapamil)
- Macrolide antibiotics (such as erythromycin, clarithromycin)
- Fluoroquinolone antibiotics (such as ciprofloxacin, norfloxacin)
- Some antivirals (such as ritonavir, indinavir)
- Herbal medicines (such as St. John's Wort)

Also, the following list includes some, but not all, of the drugs that may interact with SUTENT to affect the electrical activity of your heart:

- Antiarrhythmics (drugs that stabilize the heart rhythm function, such as procainamide, quinidine, amiodarone, sotalol, etc.)
- Antidepressants (mood disorder drugs)
- Antipsychotics (drugs to stabilize thinking and behaviour)
- Anti-asthmatics (salmeterol)
- Opioids (e.g. methadone)
- Antinauseants (e.g. granisetron, dolasetron, ondansetron)

PROPER USE OF THIS MEDICATION

You should follow the doses and instructions given by your doctor.

Usual SUTENT Adult dose:
GIST and Kidney Cancer:
50 mg taken by mouth, once daily for 4 weeks, followed by 2 weeks off (no medicine). This is called 6-week cycle. Your doctor will determine how many cycles of treatment you will need.

Pancreatic NET:
37.5 mg taken by mouth, once every day.

SUTENT can be taken with or without food. Do not drink grapefruit juice while taking SUTENT. It may increase the amount of SUTENT in the blood.

Overdose:

If you think you may have accidentally taken too many SUTENT capsules, talk to your doctor immediately or contact a poison control center. You may require medical attention.

Missed Dose:
Do not take a double dose to make up for a forgotten dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, SUTENT can have side effects which are usually mild to moderate. SUTENT can affect the way the adrenal gland works (in controlling the body's response to stress such as surgery, injury, or severe infection).

Very common side effects (these are likely to affect more than 10 in every 100 people)
- tiredness
- decreased white blood cell and platelet counts
- increased blood pressure
- mouth pain/irritation, mouth soreness, taste disturbances, upset stomach, nausea, vomiting, diarrhea, constipation, abdominal pain, dry mouth, bleeding.
- skin discoloration due to the color of sunitinib malate (yellow), hair color change, rash or blisters on the palms of the hands and soles of the feet, dry skin
- headache

Common side effects (these are likely to affect between 1 and 10 in every 100 people)
- dizziness, weakness
- loss of appetite
- infection
- heartburn
- buildup of fluid between layers of tissue in the lungs and the chest cavity

If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist**
	Only if severe	**In all cases**	
Bleeding problems (blood in urine/stool, nosebleeds) and infections		√	
Pancreatitis (inflammation of the pancreas) with symptoms such as abdominal pain, fever, nausea, vomiting		√	
Decreased thyroid gland function (hypothyroidism) with symptoms such as fatigue, constipation, dry skin, weight gain		√	
Increased thyroid gland function (hyperthyroidism and some forms of thyroiditis) with symptoms such as weight loss, sweating and irritability		√	
Decreased amount of blood pumped out of the heart with symptoms such as shortness of breath, fatigue, swollen feet and ankles		√	
Decreased white blood cell and platelet counts with symptoms such as infection, fever and bleeding		√	
Symptoms of muscle aches or weakness, or dark urine		√	
Symptoms of blood clots in the legs (pain, swelling, redness) or lungs (chest pain, shortness of breath)		√	
Symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures			√
Signs or symptoms of bone damage (osteonecrosis) in the jaw may include 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 or exposure of the bone in the jaw.		√	
Life-threatening infection of the soft tissue including the ano-genital area. Symptoms include infection around a skin injury, fever, pain, redness, swelling, or drainage of pus or blood.			√
Liver problems which include symptoms such as itching, yellow eyes or skin, dark urine, and pain or discomfort in the right upper stomach area		√	
Painful skin ulcers (pyoderma gangrenosum)		√	
Severe skin rashes that may become life threatening. They may initially appear as reddish target-like spots or circular patches often with central blisters on the trunk. The rash may progress to widespread blistering or peeling of the skin, blisters in the mouth, and ulcers in the eyes. The skin changes happen quickly and may follow fever, tiredness, headache and cough.			√

A neurological disorder called reversible posterior leukoencephalopathy syndrome with symptoms such as headache, seizures, lethargy, confusion, blindness and other visual disturbances		√	
Cholecystitis (inflammation of the gall bladder) which includes symptoms such as abdominal pain and vomiting		√	
Low blood sugar (hypoglycaemia) with symptoms such as sweating, hunger, trembling, weakness and palpitation, that may lead to loss of consciousness and seizures in some cases			√
Damage to the smallest blood vessels (TMA) that may occur inside organs such as kidney and brain. This may be caused by clotting in the small blood vessels and injury to red blood cells (TTP and HUS). Symptoms include fever, tiredness, bruising, swelling, confusion, vision loss, and seizures		√	
Symptoms of heart attack, including chest tightness, shortness of breath and sweating		√	
Symptoms of buildup of fluid between the layers of tissue in the lungs and the chest cavity include shortness of breath and chest tightness		√	
Artery Dissection (sudden severe pain in the back, chest or abdomen)		√	
Artery Aneurysm (a bulge in the wall of any artery including in the chest, arms, legs, heart, and brain): symptoms will differ by the site. They can be cough, coughing up blood. Strong pain high in your neck or in your back when you didn't hurt yourself. Problems swallowing. Hoarse voice. Unusual pulsing in your chest or abdomen.		√	

This is not a complete list of side effects. For any unexpected effects while taking SUTENT, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep out of reach and sight of children.
- Store between 15-30 °C.
- Store in the original package.
- Do not use after the expiry date (EXP) shown on the outer pack and label.
- Do not use any pack that is damaged or show signs of tampering.

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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: http://www.Pfizer.ca or by contacting Pfizer Canada ULC Medical Information at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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