

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking SUTENT?

SUTENT contains the active ingredient sunitinib. SUTENT is taken to treat renal cell carcinoma (kidney cancer), gastrointestinal stromal tumour (cancer of the stomach and bowels) and pancreatic neuroendocrine tumours (cancer in the cells of the pancreas that release hormones). For more information, see Section [1. Why am I taking SUTENT?](#) in the full CMI.

2. What should I know before I take SUTENT?

Do not take if you have ever had an allergic reaction to sunitinib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take SUTENT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SUTENT and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take SUTENT?

Your doctor will tell you the dose that you should take. The dose depends on the type of cancer. More instructions can be found in Section [4. How do I take SUTENT?](#) in the full CMI.

5. What should I know while taking SUTENT?

Things you should do	• Before starting treatment with SUTENT, you should have a dental check up. • Your doctor will need to measure and monitor your blood pressure. • You will need to have a blood test at the start of each treatment cycle or every 4 weeks if you are receiving continuous treatment with SUTENT. • You will need to have your blood glucose levels checked regularly if you have diabetes. • Use an effective method of birth control to prevent pregnancy during treatment and for at least 4 weeks after finishing treatment with SUTENT. • Tell your doctor if you are going to have surgery (an operation) or dental treatment while taking SUTENT.
Things you should not do	• Do not breastfeed while taking SUTENT. • Do not drink grapefruit juice or eat grapefruit during your treatment with SUTENT.
Driving or taking machines	• Be careful before you drive or use any machines or tools until you know how SUTENT affects you.
Looking after your medicine	• Keep SUTENT tablets in their blister pack until it is time to take them. • Keep SUTENT tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking SUTENT?](#) in the full CMI.

6. Are there any side effects?

Common side effects include tiredness, weakness, diarrhoea, constipation, nausea, vomiting, change/loss of taste, loss of appetite, weight loss, change in skin/hair colour, hair loss, tingling or rash on palms of hands or soles of feet, dry/red/scaly/itchy skin or rash, blisters; skin infections, pus formation, skin ulcers, dizziness, headache, sore tongue/mouth, dry mouth, difficulty swallowing, cold sores, cough, shortness of breath, stomach pain, wind, heart burn, indigestion, pain in fingers, arms or legs; muscle pain, joint pain, back pain, nose bleed, watery eyes, tingling or numbness of hands or feet, difficulty sleeping, depression, fever or chills, flu-like symptoms, urinary tract infections, swelling, weight gain, enlarged thyroid gland, feeling overheated, increased sweating, fast or irregular heart beat. Serious side effects include allergic reaction, fits/seizures, bleeding, low blood sugar, serious infections, toxicity or damage to the heart, gastrointestinal tract, muscle, bone, liver or brain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SUTENT®

Active ingredient(s): *sunitinib malate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking SUTENT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking SUTENT.**

Where to find information in this leaflet:

1. [Why am I taking SUTENT?](#)
2. [What should I know before I take SUTENT?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take SUTENT?](#)
5. [What should I know while taking SUTENT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking SUTENT?

SUTENT contains the active ingredient sunitinib.

SUTENT is a protein kinase inhibitor. It is used to treat cancer by preventing the activity of a group of proteins involved in the growth and spread of cancer cells.

SUTENT is taken to treat:

- renal cell carcinoma, a type of kidney cancer.
- gastrointestinal stromal tumour (GIST), cancer of the stomach and bowels.
- pancreatic neuroendocrine tumours, a rare cancer of the cells of the pancreas that release hormones.

2. What should I know before I take SUTENT?

Warnings

Do not take SUTENT if:

- you are allergic to sunitinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have high blood pressure
- have or have had an aneurysm (abnormal balloon-like swelling in the wall of an artery)
- have problems with your heart or an abnormal heart rhythm
- have or have ever had problems with your liver or kidneys
- have diabetes or problems with your thyroid

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

SUTENT should not be taken during pregnancy. Your doctor will discuss the risks with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not breastfeed while taking SUTENT.

You should have a dental check up before starting treatment with SUTENT.

Use in children

Safety and effectiveness in children have not been established for SUTENT.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with SUTENT and affect how it works. Some of these medicines include:

- ketoconazole, a medicine to treat fungal infections
- itraconazole, a medicine to treat fungal infections
- ritonavir, a medicine to treat HIV and some other infections
- erythromycin or clarithromycin, medicines to treat infections
- rifampicin, a medicine to treat tuberculosis and some other infections
- dexamethasone, a medicine to treat dermatitis, asthma and some other conditions
- phenobarbital (phenobarbitone), phenytoin or carbamazepine, medicines to treat seizures
- St. John's wort (a herbal medicine, also called *Hypericum perforatum*) to treat anxiety
- medicines used to treat irregular heart beat
- medicines called bisphosphonates, such as zoledronic acid, alendronate pamidronate or ibandronate to treat osteoporosis and some types of cancers
- medicines to treat diabetes

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SUTENT.

4. How do I take SUTENT?

How much to take

Your doctor will tell you the dose that you should take. The dose depends on the type of cancer.

For renal cell carcinoma and GIST, the usual dose is 50 mg taken once a day for 4 weeks followed by no medicine for

2 weeks, making a 6-week cycle. Your doctor will let you know how many cycles of treatment you will need.

For pancreatic neuroendocrine tumours, the usual recommended dose is 37.5 mg taken once daily.

Your doctor may change your dose or dosing schedule during treatment.

How to take it

Swallow the capsules with a glass of water.

SUTENT can be taken with or without food.

When to take it

Take the capsules at about the same time each day.

Taking them at the same time each day will help you to remember to take them.

How long to take it

Continue taking SUTENT for as long as your doctor prescribes it.

If you forget to take SUTENT

If you miss your dose at the usual time, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much SUTENT

If you think that you have taken too much SUTENT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking SUTENT?

Things you should do

- Make sure you follow your doctor's instructions and keep all appointments.
- You will need regular follow-up to make sure the treatment is working.
- Your doctor will need to measure and monitor your blood pressure.
- You will need to have a blood test at the start of each treatment cycle or every 4 weeks if you are receiving continuous treatment with SUTENT.
- You will need to have your blood glucose levels checked regularly if you have diabetes.
- Use an effective method of birth control to prevent pregnancy while being treated with SUTENT and for at least 4 weeks after finishing treatment with SUTENT.

- Tell your doctor immediately if you become pregnant while taking SUTENT.
- Tell your doctor if you are going to have surgery (an operation) or dental treatment while taking SUTENT.
- Tell any doctor, dentist or pharmacist who treats you that you are taking SUTENT.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SUTENT.

Things you should not do

- Do not drink grapefruit juice or eat grapefruit during your treatment with SUTENT.
- Do not take SUTENT to treat any other complaints unless your doctor tells you to.
- Do not give SUTENT to anyone else, even if their condition seems similar to yours.

Driving or taking machines

Be careful before you drive or use any machines or tools until you know how SUTENT affects you.

SUTENT may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything that requires you to be alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store SUTENT in a cool dry place where the temperature stays below 25°C.
- Keep the capsules in the pack until it is time to take them.

Do not store SUTENT:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
General disorders: - tiredness or weakness - loss of appetite, weight loss - increased tears, watery eyes Gastrointestinal related: - diarrhoea or constipation - nausea (feeling sick) or vomiting - upset stomach, stomach pain, wind, heart burn, indigestion - sore tongue, sore mouth, dry mouth, difficulty swallowing, cold sores Infection related: - fever or chills - flu-like symptoms - unusual urine colour, frequency or pain passing urine (urinary tract infections) Muscle or bone related: - muscle pain, joint pain, back pain - pain in fingers, arms or legs Nervous system disorders: - dizziness or headache - change in sense of taste, loss of taste - tingling or numbness of hands or feet, pins and needles - difficulty sleeping - depression Skin or hair related: - change in skin colour (yellow skin) - change in hair colour or hair loss - tingling or rash on palms of hands or soles of feet - rash, dry skin, skin redness, scaly skin, itchy skin, blisters; skin infections, pus formation, skin ulcers Lung related: - cough - shortness of breath Blood or bleeding disorders: - nose bleed Thyroid related: - swelling, weight gain, enlargement of thyroid gland - feeling overheated, increased sweating	Speak to your doctor if you have any of these common side effects and they worry you.

Common side effects	What to do
fast or irregular heart beat	

Serious side effects

Serious side effects	What to do
Heart related: - high blood pressure (often with no symptoms but can include headaches, heart palpitations or nosebleeds) Gastrointestinal related: - very bad stomach pain - leaking or discharge near anus Muscle or bone related: - muscle pain, weakness or wasting - pain, heaviness or numbness in the jaw, teeth or gums Liver related: - yellowing of skin and eyes (jaundice)	Call your doctor straight away if you notice any of these serious side effects.
Signs of allergic reaction: - shortness of breath, wheezing or trouble breathing, chest pain - swollen face, eyelids, lip, tongue or voice box; swelling under the skin Blood or bleeding disorders: - bleeding or bruising under the skin, coughing blood Infection related: - flu-like symptoms (chills, fever, sore throat, swollen glands) - infection - swelling, dark marks or blisters on any part of the body Heart/ blood vessel related: - pressure in chest - pain in the neck, shoulder or arm - swelling of feet or legs, leg pain - decrease in amount of urine - numbness or tingling on one side of the body, weakness of face, arm or leg; trouble speaking, seeing or swallowing; headache, confusion, dizziness, loss of co-ordination or balance Nervous system related: - fits, seizures Signs of hypoglycaemia:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
- decreased blood sugar level, feeling hungry, shaky or anxious Signs of brain toxicity due to high blood levels of ammonia: - lack of energy, confusion, sleepiness, decline in mental abilities, changes in consciousness	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (for example, low blood count, abnormal thyroid or liver function tests) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SUTENT contains

Active ingredient (main ingredient)	sunitinib malate equivalent to 12.5 mg, 25 mg, 37.5 mg or 50 mg of sunitinib.
Other ingredients (inactive ingredients)	mannitol croscarmellose sodium povidone magnesium stearate gelatin titanium dioxide (E171) sodium lauryl sulfate red iron oxide CI77491 (E172) (12.5 mg, 25 mg and 50 mg) yellow iron oxide CI77492 (E172) (25 mg, 37.5 mg and 50 mg) black iron oxide CI77499 (E172) (25 mg and 50 mg) Shellac propylene glycol

	sodium hydroxide (12.5 mg, 25 mg and 50 mg) ammonia (37.5 mg) butan-1-ol (37.5 mg) ethanol absolute (37.5 mg) isopropyl alcohol (37.5 mg) potassium hydroxide (37.5mg) purified water (37.5 mg)
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Do not take this medicine if you are allergic to any of these ingredients.

SUTENT capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

What SUTENT looks like

SUTENT 12.5 mg capsules have a Swedish Orange (a brownish red colour) cap and body and are printed with "Pfizer" on the cap and "STN 12.5mg" on the body in white ink.

SUTENT 25 mg capsules have a caramel-coloured cap and Swedish Orange (a brownish red colour) body and are printed with "Pfizer" on the cap and "STN 25mg" on the body in white ink.

SUTENT 37.5 mg capsules have a yellow cap and body and are printed with "Pfizer" on the cap and "STN 37.5mg" on the body in black ink.

SUTENT 50 mg capsules have a caramel-coloured cap and body and are printed with "Pfizer" on the cap and "STN 50mg" on the body in white ink.

Each blister pack contains 28 capsules.

SUTENT 12.5 mg:

AUST R 149114 (blister pack)

SUTENT 25 mg:

AUST R 149115 (blister pack)

SUTENT 37.5 mg:

AUST R 156801 (blister pack)

SUTENT 50 mg:

AUST R 149116 (blister pack)

Who distributes SUTENT

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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