

Sunitinib Sandoz®

Consumer Medicine Information (CMI) summary

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

1. Why am I taking Sunitinib Sandoz?

Sunitinib Sandoz contains the active ingredient sunitinib. Sunitinib Sandoz is used 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 Sunitinib Sandoz?](#) in the full CMI.

2. What should I know before I take Sunitinib Sandoz?

Do not use 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 Sunitinib Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sunitinib Sandoz 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 Sunitinib Sandoz?

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 Sunitinib Sandoz?](#) in the full CMI.

5. What should I know while taking Sunitinib Sandoz?

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| Things you should do | <ul style="list-style-type: none">• Before starting treatment with Sunitinib Sandoz, 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 Sunitinib Sandoz.• 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 Sunitinib Sandoz.• Tell your doctor if you are going to have surgery (an operation) or dental treatment while taking Sunitinib Sandoz. |
| Things you should not do | <ul style="list-style-type: none">• Do not breastfeed while taking Sunitinib Sandoz.• Do not drink grapefruit juice or eat grapefruit during your treatment with Sunitinib Sandoz. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Sunitinib Sandoz affects you. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep Sunitinib Sandoz tablets in their blister pack until it is time to take them.• Keep Sunitinib Sandoz 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 Sunitinib Sandoz?](#) 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.

Sunitinib Sandoz®

Active ingredient(s): *sunitinib*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking Sunitinib Sandoz?

Sunitinib Sandoz contains the active ingredient sunitinib. Sunitinib Sandoz 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.

Sunitinib Sandoz is used 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 Sunitinib Sandoz?

Warnings

Do not use Sunitinib Sandoz 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 use 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.

Sunitinib Sandoz 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 Sunitinib Sandoz.

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

Use in children

Safety and effectiveness in children have not been established for Sunitinib Sandoz.

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 Sunitinib Sandoz 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 Sunitinib Sandoz.

4. How do I take Sunitinib Sandoz?

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 Sunitinib Sandoz

Swallow the capsules with a glass of water.

Sunitinib Sandoz can be taken with or without food.

When to take Sunitinib Sandoz

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 Sunitinib Sandoz

Continue taking Sunitinib Sandoz for as long as your doctor prescribes it.

If you forget to use Sunitinib Sandoz

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 use too much Sunitinib Sandoz

If you think that you have used too much Sunitinib Sandoz, 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 Sunitinib Sandoz?

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 Sunitinib Sandoz.
- 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 Sunitinib Sandoz and for at least 4 weeks after finishing treatment with Sunitinib Sandoz.
- Tell your doctor immediately if you become pregnant while taking Sunitinib Sandoz.
- Tell your doctor if you are going to have surgery (an operation) or dental treatment while taking Sunitinib Sandoz.
- Tell any doctor, dentist or pharmacist who treats you that you are taking Sunitinib Sandoz.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Sunitinib Sandoz.

Things you should not do

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

Driving or using machines

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

Sunitinib Sandoz may cause dizziness 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 Sunitinib Sandoz 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 it:

- 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 use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use 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 |
|---|---|
| <p>General disorders:</p> <ul style="list-style-type: none"> tiredness or weakness loss of appetite, weight loss increased tears, watery eyes <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> 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 <p>Infection related:</p> <ul style="list-style-type: none"> fever or chills flu-like symptoms unusual urine colour, frequency or pain passing urine (urinary tract infections) <p>Muscle or bone related:</p> <ul style="list-style-type: none"> muscle pain, joint pain, back pain pain in fingers, arms or legs <p>Nervous system disorders:</p> <ul style="list-style-type: none"> dizziness or headache change in sense of taste, loss of taste tingling or numbness of hands or feet, pins and needles difficulty sleeping depression <p>Skin or hair related:</p> <ul style="list-style-type: none"> 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 <p>Lung related:</p> <ul style="list-style-type: none"> cough shortness of breath <p>Blood or bleeding disorders:</p> <ul style="list-style-type: none"> nose bleed | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

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| <p>Thyroid related:</p> <ul style="list-style-type: none"> swelling, weight gain, enlargement of thyroid gland feeling overheated, increased sweating fast or irregular heart beat | |
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Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Heart related:</p> <ul style="list-style-type: none"> high blood pressure (often with no symptoms but can include headaches, heart palpitations or nosebleeds) <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> very bad stomach pain leaking or discharge near anus <p>Muscle or bone related:</p> <ul style="list-style-type: none"> muscle pain, weakness or wasting pain, heaviness or numbness in the jaw, teeth or gums <p>Liver related:</p> <ul style="list-style-type: none"> yellowing of skin and eyes (jaundice) | <p>Call your doctor straight away, if you notice any of these serious side effects.</p> |
| <p>Signs of allergic reaction:</p> <ul style="list-style-type: none"> shortness of breath, wheezing or trouble breathing, chest pain swollen face, eyelids, lip, tongue or voice box; swelling under the skin <p>Blood or bleeding disorders:</p> <ul style="list-style-type: none"> bleeding or bruising under the skin, coughing blood <p>Infection related:</p> <ul style="list-style-type: none"> flu-like symptoms (chills, fever, sore throat, swollen glands) infection swelling, dark marks or blisters on any part of the body <p>Heart/ blood vessel related:</p> <ul style="list-style-type: none"> 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 <p>Nervous system related:</p> <ul style="list-style-type: none"> fits, seizures | <p>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.</p> |

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| <p>Signs of hypoglycaemia:</p> <ul style="list-style-type: none"> decreased blood sugar level, feeling hungry, shaky or anxious <p>Signs of brain toxicity due to high blood levels of ammonia:</p> <ul style="list-style-type: none"> 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/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 Sunitinib Sandoz contains

| | |
|---|--|
| Active ingredient (main ingredient) | sunitinib |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> microcrystalline cellulose mannitol croscarmellose sodium povidone magnesium stearate gelatin titanium dioxide iron oxide red(12.5 mg, 25 mg and 50 mg) iron oxide yellow (25 mg, 37.5 mg and 50 mg) iron oxide black (25 mg and 50 mg) OPACODE monogramming ink S - 1 -18086 WHITE (12.5 mg, 25 mg and 50 mg) OPACODE monogramming ink S - 1 -277002 BLACK (37.5 mg) |
| Potential allergens | mannitol |

Do not take this medicine if you are allergic to any of these ingredients.

What Sunitinib Sandoz looks like

Sunitinib Sandoz 12.5 mg - gelatin capsules with orange cap and orange body, printed with white ink "12.5 mg" on the body and containing yellow to orange granules. Each blister pack contains 28 capsules (Aust R 318077).

Sunitinib Sandoz 25 mg - gelatin capsules with caramel cap and orange body, printed with white ink "25 mg" on the body and containing yellow to orange granules. Each blister pack contains 28 capsules (Aust R 318075).

Sunitinib Sandoz 37.5 mg - gelatin capsules with yellow cap and yellow body, printed with black ink "37.5 mg" on the body and containing yellow to orange granules. Each blister pack contains 28 capsules (Aust R 318074).

Sunitinib Sandoz 50 mg - gelatin capsules with caramel cap and caramel body, printed with white ink "50 mg" on the body and containing yellow to orange granules. Each blister pack contains 28 capsules (Aust R 318073).

Not all presentations may be marketed.

Who distributes Sunitinib Sandoz

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