

SUNITINIB SANDOZ®

sunitinib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sunitinib Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sunitinib Sandoz against the benefits it is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Sunitinib Sandoz is used for

Sunitinib Sandoz is used in the treatment of renal cell carcinoma, a type of kidney cancer.

Sunitinib Sandoz is used to treat gastrointestinal stromal tumour (GIST). GIST is a cancer of the stomach and bowels. It is caused by the uncontrolled growth of cells in the wall of the stomach or bowel.

Sunitinib Sandoz slows down the growth of these cells.

Sunitinib Sandoz is also used to treat pancreatic neuroendocrine tumours. This is a rare cancer in the cells of the pancreas that release hormones.

Ask your doctor if you have any questions about why Sunitinib Sandoz has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Sunitinib Sandoz is only available with a doctor's prescription. It is not addictive.

Use in children

The safety and efficacy of Sunitinib Sandoz have not been established in children.

Before you take Sunitinib Sandoz

When you must not take it

Do not take Sunitinib Sandoz if you have ever had an allergic reaction to

- **sunitinib (the active ingredient in Sunitinib Sandoz)**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use Sunitinib Sandoz after the expiry date printed on the pack.

Do not use Sunitinib Sandoz if the packaging shows signs of tampering.

Before you start to take it

You must tell your doctor if:

- **you have high blood pressure**
- **you have or have had an aneurysm (abnormal balloon-like swelling in the wall of an artery)**
- **you have problems with your heart**
- **you have or have ever had problems with your liver or kidneys**
- **you are pregnant or planning to become pregnant**
Sunitinib Sandoz should not be used during pregnancy. Your doctor will discuss the risks with you.
- **you are breastfeeding.**
You should not breastfeed while taking Sunitinib Sandoz.

You should have a dental check up before taking Sunitinib Sandoz.

Taking other medicines

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

Some medicines and Sunitinib Sandoz may interfere with each other. 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 infection
- erythromycin, a medicine to treat infections

- clarithromycin, a medicine to treat infections
- rifampicin, a medicine to treat tuberculosis and some other infections
- dexamethasone, a medicine to treat dermatitis, asthma and some other conditions
- phenytoin, a medicine to treat seizures
- carbamazepine, a medicine to treat seizures
- phenobarbital (phenobarbitone), a medicine 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.

You may need to take different amounts of your medicines or you may need to use different medicines. Your doctor will advise you.

How to take Sunitinib Sandoz

Follow all directions given to you by your doctor carefully.

These directions 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.

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.

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.

Sunitinib Sandoz can be taken with or without food.

How long to take it

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

If you forget to take it

If you miss a dose, do not take an additional dose. Take your usual dose on the next day.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Phone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Sunitinib Sandoz. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

While you are taking Sunitinib Sandoz

Things you must 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 measure your blood pressure. You will also have blood tests to check for side effects.

Use a proven method of birth control (contraception) 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 must not do

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.

Things to be careful of

Avoid drinking grapefruit juice while you are being treated with Sunitinib Sandoz.

Grapefruit juice may interact with Sunitinib Sandoz and affect how your body uses this medicine.

Be careful driving, operating machinery or doing jobs that require you to be alert, until you know how Sunitinib Sandoz affects you.

Sunitinib Sandoz may make some people feel very tired or dizzy.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sunitinib Sandoz.

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Medicines can affect people in different ways.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- tiredness
- diarrhoea
- nausea (feeling sick) or vomiting
- change in sense of taste, loss of taste
- loss of appetite, weight loss
- change in skin colour
- change in hair colour
- 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
- headache
- constipation
- sore tongue, sore mouth, dry mouth, difficulty swallowing, cold sores
- cough
- upset stomach, stomach pain, wind, heart burn, indigestion
- pain in fingers, arms or legs
- weakness
- muscle pain, joint pain, back pain
- dizziness
- hair loss
- nose bleed

- increased tears, watery eyes
- tingling or numbness of hands or feet; pins and needles
- difficulty sleeping
- depression
- unusual urine colour, frequency or pain passing urine
- swelling, weight gain, enlargement of thyroid gland
- feeling overheated, increased sweating
- fast or irregular heart beat.

These are the more common side effects.

Tell your doctor immediately if you get any of the following side effects:

- shortness of breath, wheezing or trouble breathing, chest pain
- swelling of feet or legs, leg pain
- swollen face, eyelids, lip, tongue or voice box; swelling under the skin
- bleeding or bruising under the skin; coughing blood
- flu-like symptoms (chills, fever, sore throat, swollen glands)
- high blood pressure
- very bad stomach pain
- leaking or discharge near anus
- fits, seizures
- infection
- swelling, dark marks or blisters on any part of the body
- muscle pain, weakness or wasting
- decrease in amount of urine
- yellowing of skin and eyes (jaundice)
- 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
- pain or numbness in the jaw, teeth or gums
- decreased blood sugar level, feeling hungry, shaky or anxious
- pain in the neck, shoulder or arm

- pressure in the chest.

The above side effects may be serious. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Sunitinib Sandoz

Storage

Keep your capsules in the original container until it is time to take them.

Store Sunitinib Sandoz in a cool dry place.

Do not leave Sunitinib Sandoz or any other medicine in the car or on window sills.

Do not store Sunitinib Sandoz or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep the capsules where children cannot reach them.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left.

Product description

What it looks like

Sunitinib Sandoz 12.5 mg capsules are gelatin capsules with orange cap and orange body, printed with white

ink “12.5 mg” on the body and containing yellow to orange granules.

Sunitinib Sandoz 25 mg capsules are gelatin capsules with caramel cap and orange body, printed with white ink “25 mg” on the body and containing yellow to orange granules.

Sunitinib Sandoz 37.5 mg capsules are gelatin capsules with yellow cap and yellow body, printed with black ink “37.5 mg” on the body and containing yellow to orange granules.

Sunitinib Sandoz 50 mg capsules are 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.

Each bottle contains 30 capsules.

Not all presentations may be marketed.

Ingredients

Sunitinib Sandoz 12.5 mg capsule contains 12.5 mg of sunitinib.

Sunitinib Sandoz 25 mg capsule contains 25 mg of sunitinib.

Sunitinib Sandoz 37.5 mg capsule contains 37.5 mg of sunitinib.

Sunitinib Sandoz 50 mg capsule contains 50 mg of sunitinib.

The capsules also contain:

- 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).

Sunitinib Sandoz capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sunitinib Sandoz is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Australian Registration Numbers

Sunitinib Sandoz 12.5 mg:

AUST R 318077 (blister pack)

Sunitinib Sandoz 25 mg:

AUST R 318075 (blister pack)

Sunitinib Sandoz 37.5 mg:

AUST R 318074 (blister pack)

Sunitinib Sandoz 50 mg:

AUST R 318073 (blister pack)

Date of preparation

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