

SUNITINIB MSN

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 using Sunitinib MSN?

Sunitinib MSN contains the active ingredient sunitinib. Sunitinib MSN is used in treatment of renal cell carcinoma, treatment of gastrointestinal stromal tumour (GIST) and treatment of pancreatic neuroendocrine tumours.

For more information, see Section [1. Why am I using Sunitinib MSN?](#) in the full CMI.

2. What should I know before I use Sunitinib MSN?

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 use Sunitinib MSN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sunitinib MSN 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 use Sunitinib MSN?

- Follow all directions given to you by your doctor carefully.

More instructions can be found in Section [4. How do I use Sunitinib MSN?](#) in the full CMI.

5. What should I know while using Sunitinib MSN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Sunitinib MSN.• Make sure you follow your doctor's instructions and keep all appointments.• Use a proven method of birth control to prevent pregnancy while being treated with Sunitinib MSN and for at least 4 weeks after finishing treatment with Sunitinib MSN.• Tell your doctor immediately if you become pregnant while taking Sunitinib MSN.• Tell your doctor if you are going to have surgery, an operation or dental treatment while taking Sunitinib MSN.• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Sunitinib MSN.
Things you should not do	<ul style="list-style-type: none">• Do not take Sunitinib MSN to treat any other complaints unless your doctor tells you to.• Do not give Sunitinib MSN to anyone else, even if their condition seems similar to yours.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert, until you know how Sunitinib MSN affects you.• Sunitinib MSN may make some people feel very tired or dizzy.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the original container until it is time to take them.• Store Sunitinib MSN in a cool dry place.• Do not leave Sunitinib MSN or any other medicine in the car or on window sills.• Do not store Sunitinib MSN or any other medicine in the bathroom or near a sink.

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

6. Are there any side effects?

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.

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 MSN

Active ingredient(s): *Sunitinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sunitinib MSN. **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 MSN.**

Where to find information in this leaflet:

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

1. Why am I taking Sunitinib MSN?

Sunitinib MSN contains the active ingredient sunitinib. Sunitinib MSN is used in the treatment of renal cell carcinoma, a type of kidney cancer.

Sunitinib MSN 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 MSN slows down the growth of these cells.

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

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

Warnings

Do not use Sunitinib MSN if:

- you are allergic to sunitinib, or any of the ingredients listed at the end of this leaflet.**
Symptoms of 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.

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**

- have or have ever had problems with your liver or kidneys**
- should have a dental check up before taking Sunitinib MSN.**

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

You must tell your doctor if you are pregnant or planning to become pregnant.

Sunitinib MSN should not be used during pregnancy. Your doctor will discuss the risks with you.

Tell your doctor if you are breastfeeding.

You should not breastfeed while taking Sunitinib MSN.

Children

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

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 MSN and affect how it works. Some of these medicines include:

- Ketoconazole, a medicine to treat fungal infections
- Itraconazole, a medicine to treat fungal infection
- 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

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 MSN.

4. How do I use Sunitinib MSN?

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.
- Follow the instructions provided and use Sunitinib MSN until your doctor tells you to stop.

When to take Sunitinib MSN

- Sunitinib MSN should be used at about the same time each day.

How to take Sunitinib MSN

- Swallow the capsules with a glass of water.
- Sunitinib MSN can be taken with or without food.

How long to take Sunitinib MSN

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

If you forget to take Sunitinib MSN

Sunitinib MSN should be used regularly at the same time each day. If you miss your dose at the usual time, 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 dose you missed.

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

If you take too much Sunitinib MSN

If you think that you have taken too much Sunitinib MSN, 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 using Sunitinib MSN?

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

Remind any doctor, dentist or pharmacist you visit that you are using Sunitinib MSN.

Call your doctor straight away if you:

- Are going to have surgery, an operation or dental treatment while taking Sunitinib MSN.

Things you should not do

- Do not take Sunitinib MSN to treat any other complaints unless your doctor tells you to.
- Do not give Sunitinib MSN 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 MSN. Grapefruit juice may interact with Sunitinib MSN and affect how your body uses this medicine.

Driving or using machines

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

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

Looking after your medicine

Store it in a cool dry place away from moisture, heat or sunlight where the temperature remains below 25°C; for example, do not store it:

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

Keep it where young children cannot reach it.

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.

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

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> 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. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> Shortness of breath, wheezing or trouble breathing, chest pain 	<p>Call your doctor straight away, or go straight</p>

<ul style="list-style-type: none"> 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 coordination 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 	<p>to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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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.

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 MSN contains

Active ingredient (main ingredient)	Sunitinib
Other ingredients (inactive ingredients)	Mannitol Croscarmellose sodium pregelatinised maize starch

	Magnesium stearate Gelatin Titanium dioxide Iron oxide red Iron oxide yellow Iron oxide black Tek print black/white ink
Potential allergens	N/A

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

What Sunitinib MSN looks like

Sunitinib MSN 12.5 mg capsules are hard gelatin capsules with orange opaque body imprinted with “6” and orange opaque cap imprinted with “MS” in white ink, free from physical defects.

Aust R 370769 (blister pack)

Aust R 370765 (bottle)

Sunitinib MSN 25 mg capsules are hard gelatin capsules with orange opaque body imprinted with “7” and caramel opaque cap imprinted with “MS” in white ink, free from physical defects.

Aust R 370764 (blister pack)

Aust R 370766 (bottle)

Sunitinib MSN 37.5 mg capsules are hard gelatin capsules with yellow opaque body imprinted with “8” and yellow opaque cap imprinted with “MS” in black ink, free from physical defects.

Aust R 370770 (blister pack)

Aust R 370771 (bottle)

Sunitinib MSN 50 mg capsules are hard gelatin capsules with caramel opaque body imprinted with “9” and caramel opaque cap imprinted with “MS” in white ink, free from physical defects.

Aust R 370768 (blister pack)

Aust R 370767 (bottle)

Sunitinib MSN 12.5 mg, 25 mg, 37.5 mg and 50 mg capsules are supplied in HDPE bottles or PVC/Aclar-Al blister packs containing 28 or 30 capsules.

Who distributes Sunitinib MSN

Cipla Australia Pty. Ltd

Level 1, 132 Albert Road, South Melbourne, VIC 3205

Australia

This leaflet was prepared in April 2023.