

**MEDICATION GUIDE**  
**Sunitinib Malate (soo ni' ti nib mal' ate) Capsules**

**Rx only**

**What is the most important information I should know about sunitinib malate capsules?**

**Sunitinib malate capsules can cause serious side effects including:**

- **Severe liver problems, that can lead to death. Tell your healthcare provider right away if you develop any of the following signs and symptoms of liver problems during treatment with sunitinib malate capsules:**

- itching
- yellow eyes or skin
- dark urine
- pain or discomfort in the right upper stomach area

Your healthcare provider should do blood tests to check your liver function before you start taking and during treatment with sunitinib malate capsules. Your healthcare provider may temporarily stop, reduce your dose, or permanently stop treatment with sunitinib malate capsules if you develop liver problems.

See “What are the possible side effects of sunitinib malate capsules?” for more information about side effects.

**What are sunitinib malate capsules?**

Sunitinib malate capsules are prescription medicine used to treat:

- a rare cancer of the stomach, bowel, or esophagus called gastrointestinal stromal tumor (GIST) and when:
  - you have taken the medicine imatinib mesylate and it did not stop the cancer from growing, or
  - you cannot take imatinib mesylate.
- advanced kidney cancer (advanced renal cell carcinoma or RCC).
- adults with kidney cancer that has not spread (localized), and who are at high risk of RCC coming back again after having kidney surgery.
- a type of pancreatic cancer called pancreatic neuroendocrine tumors (pNET), that has progressed and cannot be treated with surgery.

It is not known if sunitinib malate capsules are safe and effective in children.

**Before taking sunitinib malate capsules tell your healthcare provider about all of your medical conditions, including if you:**

- have any heart problems
- have high blood pressure
- have thyroid problems
- have a history of low blood sugar or diabetes
- have kidney function problems (other than cancer)
- have liver problems
- have any bleeding problem
- plan to have surgery or have had a recent surgery. You should stop taking sunitinib malate capsules at least 3 weeks before planned surgery. See “What are the possible side effects of sunitinib malate capsules?”
- have seizures
- have or have had pain in the mouth, teeth or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth
- are pregnant or plan to become pregnant. Sunitinib malate capsules can harm your unborn baby.

**Females** who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with sunitinib malate capsules.
- You should use effective birth control (contraception) during treatment and for at least 4 weeks after your last dose of sunitinib malate capsules.
- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with sunitinib malate capsules.

**Males** with female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 7 weeks after your last dose of sunitinib malate capsules. Sunitinib malate capsules may cause fertility problems in males and females. Tell your healthcare provider if this is a concern for you.

- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with sunitinib malate capsules and for at least 4 weeks (1 month) after the last dose.

Tell all of your healthcare providers and dentists that you are taking sunitinib malate capsules. They should talk to the healthcare provider who prescribed sunitinib malate capsules for you, before you have **any** surgery, or medical or dental procedure.

**Tell your healthcare provider about all the medicines you take**, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Using sunitinib malate capsules with certain other medicines can cause serious side effects.

You may have an increased risk of severe jawbone problems (osteonecrosis) if you take sunitinib malate capsules and a bisphosphonate medicine. **Especially tell** your healthcare provider if you are taking or have taken an osteoporosis medicine.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take sunitinib malate capsules?**

- Take sunitinib malate capsules exactly the way your healthcare provider tells you.
- Take sunitinib malate capsule 1 time each day with or without food.
- If you take sunitinib malate capsules for GIST or RCC, you will usually take your medicine for 4 weeks (28 days) and then stop for 2 weeks (14 days). This is 1 cycle of treatment. You will repeat this cycle for as long as your healthcare provider tells you to.
- If you take sunitinib malate capsules for pNET, take it 1 time each day until your healthcare provider tells you to stop.
- Do not drink grapefruit juice or eat grapefruit during your treatment with sunitinib malate capsules. They may cause you to have too much sunitinib malate in your body.
- Your healthcare provider may do blood tests before each cycle of treatment to check you for side effects.
- If you miss a dose of sunitinib malate capsules by less than 12 hours, take the missed dose right away. If you miss a dose of sunitinib malate capsules by more than 12 hours, just take your next dose at your regular time. Do not make up the missed dose. Tell your healthcare provider about any missed dose.
- Call your healthcare provider right away, if you take too much sunitinib malate capsules.

**What are possible side effects of sunitinib malate capsules?**

**Sunitinib malate capsules may cause serious side effects, including:**

- See “What is the most important information I should know about sunitinib malate capsules?”

- **Heart problems.** Heart problems may include heart failure, heart attack and heart muscle problems (cardiomyopathy) that can lead to death. Tell your healthcare provider if you feel very tired, are short of breath, or have swollen feet and ankles.

- **Abnormal heart rhythm changes. Changes in the electrical activity of your heart called QT prolongation can cause irregular heart beats that can be life threatening.** Your healthcare provider may do electrocardiograms and blood tests (electrolytes) to watch for these problems during your treatment with sunitinib malate capsules. Tell your healthcare provider right away if you feel dizzy, faint, or have abnormal heartbeats during your treatment with sunitinib malate capsules

- you feel faint or lightheaded, or you pass out
- feel your heart beat is irregular or fast
- dizziness

- **High blood pressure.** High blood pressure is common with sunitinib malate capsules, and may sometimes be severe. Follow your healthcare provider’s instructions about having your blood pressure checked regularly. Call your healthcare provider if your blood pressure is high, or if you have any of the following signs or symptoms of high blood pressure:

- severe headache
- dizziness
- lightheadedness
- change in vision

Your healthcare provider may prescribe medicine for you to treat high blood pressure, if needed.

- **Bleeding problems.** Bleeding is common with sunitinib malate capsules, but sunitinib malate capsules can also cause severe bleeding problems that can lead to death. Your healthcare provider will monitor you for bleeding and may do blood tests if needed. Call your healthcare provider right away if you have any of these symptoms or a serious bleeding problem during treatment with sunitinib malate capsules, including:

- painful, swollen stomach (abdomen)
- bloody urine
- vomiting blood
- headache
- coughing up blood
- change in your mental status
- black, sticky stools

- **Serious stomach and intestinal problems, that can sometimes lead to death.** Some people have had tears in their stomach or intestine (perforation), or have developed an abnormal opening between the stomach and intestine (fistula). Get medical help right away if you get stomach-area (abdominal) pain that does not go away or is severe during treatment with sunitinib malate capsules.

- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells and may lead to death. TLS can cause kidney failure and the need for dialysis treatment,

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abnormal heart rhythm, seizure, and sometimes death. Your healthcare provider may do blood tests to check you for TLS.

- **Abnormal changes in the brain (Reversible Posterior Leukoencephalopathy Syndrome[RPLS]).** RPLS can cause a collection of symptoms including headache, confusion, and vision loss. Some people who have taken sunitinib malate capsules have developed RPLS that can lead to death.
- **Thrombotic microangiopathy (TMA) including thrombotic thrombocytopenia purpura (TTP) and hemolytic uremic syndrome (HUS).** TMA is a condition that involves injury to the smallest blood vessels, and blood clots that can happen while taking sunitinib malate capsules. TMA is accompanied by a decrease in red cells and cells that are involved with clotting. TMA may harm your body's organs such as the brain and kidneys, and can sometimes lead to death.
- **Protein in your urine.** Some people who have taken sunitinib malate capsules have developed protein in their urine, and in some cases, kidney problems that can lead to death. Your healthcare provider will check you for this problem.
- **Serious skin and mouth reactions.** Treatment with sunitinib malate capsules has caused severe skin reactions that can lead to death, including:
  - severe rash with blisters or peeling of the skin.
  - painful sores or ulcers on the skin, lips or inside the mouth.
  - tissue damage (necrotizing fasciitis).

If you have any signs or symptoms of severe skin reactions, stop taking sunitinib malate capsules and call your healthcare provider or get medical help right away.

- **Thyroid problems.** Your healthcare provider may do tests to check your thyroid function during sunitinib malate capsules treatment. Tell your healthcare provider if you have any of the following signs and symptoms during your treatment with sunitinib malate capsules:
  - tiredness that gets worse and does not go away
  - loss of appetite
  - feeling nervous or agitated, tremors
  - sweating
  - nausea or vomiting
  - diarrhea
  - fast heart beat
  - weight gain or weight loss
  - problems with heat
  - feeling depressed
  - irregular menstrual periods or no menstrual periods
  - headache
  - hair loss

- **Low blood sugar (hypoglycemia).** Low blood sugar can happen with sunitinib malate capsules, and may cause you to become unconscious, or you may need to be hospitalized. Low blood sugar with sunitinib malate capsules may be worse in people who have diabetes and take antidiabetic medicines. Your healthcare provider should check your blood sugar levels regularly during treatment with sunitinib malate capsules and may need to adjust the dose of your antidiabetic medicines. Call your healthcare provider right away if you have any of the following signs or symptoms of low blood sugar during your treatment with sunitinib malate capsules:

- headache
- drowsiness
- weakness
- dizziness
- confusion
- irritability
- hunger
- fast heart beat
- sweating
- feeling jittery

- **Jawbone problems (osteonecrosis).** Severe jawbone problems have happened in some people who take sunitinib malate capsules. Certain risk factors such as taking a bisphosphonate medicine or having dental disease may increase your risk of getting osteonecrosis. Your healthcare provider may tell you to see your dentist before you start taking sunitinib malate capsules. Your healthcare provider may tell you to avoid dental procedures, if possible, during your treatment with sunitinib malate capsules, especially if you are receiving a bisphosphonate medicine into a vein (intravenous). Tell your healthcare provider if you plan to have any dental procedures before or during treatment with sunitinib malate capsules.

- You should stop taking sunitinib malate capsules at least 3 weeks before planned dental procedures.
- Your healthcare provider should tell you when you may start taking sunitinib malate capsules again after dental procedures.

- **Wound healing problems.** Wound healing problems have happened in some people who take sunitinib malate capsules. Tell your healthcare provider if you plan to have any surgery before or during treatment with sunitinib malate capsules.
  - You should stop taking sunitinib malate capsules at least 3 weeks before planned surgery.

- Your healthcare provider should tell you when you may start taking sunitinib malate capsules again after surgery.

**Your healthcare provider may temporarily stop, reduce your dose, or permanently stop treatment with sunitinib malate capsules if you develop serious side effects.**

**Common side effects of sunitinib malate capsules include:**

- tiredness
- weakness
- diarrhea
- pain, swelling or sores inside of your mouth
- nausea
- loss of appetite
- indigestion
- vomiting
- stomach-area (abdominal) pain
- blisters or rash on the palms of your hands and soles of your feet
- high blood pressure
- taste changes
- low platelet counts

The medicine in sunitinib malate capsules is yellow, and it may make your skin look yellow. Your skin and hair may get lighter in color. Sunitinib malate capsules may also cause other skin problems including: dryness, thickness or cracking of the skin.

These are not all of the possible side effects of sunitinib malate capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How do I store sunitinib malate capsules?**

- Store sunitinib malate capsules at room temperature, between 68°F to 77°F (20°C to 25°C).

**Keep sunitinib malate capsules and all medicines out of the reach of children.**

**General information about the safe and effective use of sunitinib malate capsules.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sunitinib malate capsules for a condition for which it was not prescribed. Do not give sunitinib malate capsules to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about sunitinib malate capsules that is written for health professionals.

**What are the ingredients in sunitinib malate capsules?**

**Active ingredient:** sunitinib malate

**Inactive ingredients:** croscarmellose sodium, magnesium stearate, mannitol, povidone (K-30).

**Reddish brown gelatin capsule shells:** ferric oxide red and titanium dioxide.

**Caramel gelatin capsule shells:** ferric oxide red, ferric oxide yellow, ferrousferrous oxide and titanium dioxide.

**Yellow gelatin capsule shells:** ferric oxide yellow and titanium dioxide.

**White printing ink:** potassium hydroxide, shellac and titanium dioxide.

**Black printing ink:** ferrousferrous oxide, potassium hydroxide and shellac.

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Manufactured by:

**Sun Pharmaceutical Industries Ltd.**

Survey No. 1012, Dadra-396 193,  
U.T. of D & NH and Daman & Diu, India.

Distributed by:

**Sun Pharmaceutical Industries, Inc.**

Cranbury, NJ 08512

October 2023

FDA-05

For more information, call 1-800-818-4555.

This Medication Guide has been approved by the U.S. Food and Drug Administration