

**Patient Information**  
**Sorafenib (soe raf' e nib)**  
**tablets, oral**

**What are Sorafenib tablets?**

Sorafenib tablets is a prescription medicine used to treat:

- a type of liver cancer called hepatocellular carcinoma (HCC) that cannot be removed by surgery
- a type of kidney cancer called renal cell carcinoma (RCC)
- a type of thyroid cancer called differentiated thyroid carcinoma (DTC) that can no longer be treated with radioactive iodine and is progressing

It is not known if sorafenib tablets are safe and effective in children.

**Do not take sorafenib tablets if you:**

- are allergic to sorafenib or any of the other ingredients in sorafenib tablets. See the end of this leaflet for a complete list of ingredients in sorafenib tablets.
- have squamous cell lung cancer and receive carboplatin and paclitaxel.

**Before taking sorafenib tablets, tell your healthcare provider about all of your medical conditions including if you:**

- have heart problems including a condition called “congenital long QT syndrome”
- have chest pain
- have abnormal magnesium, potassium, or calcium blood levels
- have bleeding problems
- have high blood pressure
- plan to have surgery or have had a recent surgery. You should stop taking sorafenib tablets at least 2 weeks before planned surgery. See “**What are the possible side effects of sorafenib tablets?**”
- are pregnant or plan to become pregnant. Sorafenib tablets may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with sorafenib tablets.

**For females** who are able to become pregnant:

- Your healthcare should do a pregnancy test before you start treatment with sorafenib tablets.
- Use effective birth control (contraception) during your treatment with sorafenib tablets and for 6 months after the last dose of sorafenib tablets.

**For males** with female partners who are able to become pregnant:

- Use effective birth control (contraception) during your treatment with sorafenib tablets and for 3 months after the last dose of sorafenib tablets.
- are breastfeeding or plan to breastfeed. It is not known if sorafenib passes into your breast milk. Do not breastfeed during treatment with sorafenib tablets and for 2 weeks after receiving the last dose of sorafenib tablets.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take the medicine warfarin.

**How should I take sorafenib tablets?**

- Take sorafenib tablets exactly as your healthcare provider tells you to take it.
- Take sorafenib tablets 2 times a day. Your healthcare provider may change your dose,

temporarily stop treatment or completely stop treatment with sorafenib tablets if you have side effects.

- Take sorafenib tablets without food (at least 1 hour before or 2 hours after a meal).
- If you miss a dose of sorafenib tablets, skip the missed dose, and take your next dose at your regular time. Do not double your dose of sorafenib tablets.
- If you take too much sorafenib tablets call your doctor or go to the nearest hospital emergency room right away.

### **What are the possible side effects of sorafenib tablets?**

#### **Sorafenib tablets may cause serious side effects, including:**

- **decreased blood flow to the heart, heart attack and heart failure.** Get emergency help right away if you get symptoms such as chest pain, shortness of breath, racing heartbeat, swelling in lower legs, feet and abdomen, feel lightheaded or faint, tiredness, nausea, vomiting, or sweat a lot.
- **increased risk of bleeding. Bleeding is a common side effect of sorafenib tablets** that can be serious and can lead to death. Tell your healthcare provider right away if you have any signs of bleeding during treatment with sorafenib tablets:
  - vomiting blood or if your vomit looks like coffee-grounds
  - pink or brown urine
  - red or black (looks like tar) stools
  - coughing up blood or blood clots
  - heavier than normal menstrual cycle
  - unusual vaginal bleeding
  - frequent nose bleeds
  - bruising
- **high blood pressure.** High blood pressure is a common side effect of sorafenib tablets and can be serious. Your blood pressure should be checked every week during the first 6 weeks of starting sorafenib tablets. Your blood pressure should be checked regularly and any high blood pressure should be treated during treatment with sorafenib tablets.
- **skin problems.** A condition called hand-foot skin reactions and skin rash are common with sorafenib tablets treatment and can be severe. Sorafenib tablets may also cause severe skin and mouth reactions that can be life-threatening. Tell your healthcare provider if you have any of the following symptoms:
  - skin rash
  - skin redness
  - pain or swelling
  - blistering and peeling of your skin
  - blistering and peeling on the inside of your mouth
  - blisters on the palms of your hand or soles of your feet
- **an opening in the wall of your stomach or intestines (gastrointestinal perforation).** Tell your healthcare provider right away if you get fever, nausea, vomiting or severe stomach (abdominal) pain.
- **risk of wound healing problems.** Wounds may not heal properly during sorafenib tablets treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with sorafenib tablets.
  - You should stop taking sorafenib tablets at least 10 days before planned surgery.
  - Your healthcare provider should tell you when you may start taking sorafenib tablets again after surgery.

- **changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life-threatening. Your healthcare provider may do tests during your treatment with sorafenib tablets to check the levels of potassium, magnesium, and calcium in your blood, and check the electrical activity of your heart with an electrocardiogram (ECG). Tell your healthcare provider right away if you feel faint, lightheaded, dizzy or feel your heart beating irregularly or fast during your treatment with sorafenib tablets.
- **liver problems (drug-induced hepatitis).** Sorafenib tablets may cause liver problems that may lead to liver failure and death. Your healthcare provider will do blood tests to check your liver function regularly during your treatment with sorafenib tablets. Tell your healthcare provider right away if you develop any of the following symptoms:
  - yellowing of your skin or the whites of your eyes
  - dark “tea-colored” urine
  - light-colored bowel movements (stools)
  - worsening nausea or vomiting
  - pain on the right side of your stomach area
  - bleeding or bruising more easily than normal
  - loss of appetite
- **change in thyroid hormone levels.** If you have differentiated thyroid cancer, you can have changes in your thyroid hormone levels during treatment with sorafenib tablets. Your healthcare provider may need to change your dose of thyroid medicine during treatment with sorafenib tablets. Your healthcare provider should check your thyroid hormone levels every month during treatment with sorafenib tablets.

**The most common side effects of sorafenib tablets include:**

- diarrhea (frequent or loose bowel movements)
- tiredness
- infection
- hair thinning or patchy hair loss
- rash
- weight loss
- loss of appetite
- nausea
- stomach-area (abdomen) pain
- low blood calcium levels in people with differentiated thyroid cancer

Sorafenib tablets may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

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

**How should I store sorafenib tablets?**

- Store Sorafenib tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store sorafenib tablets in a dry place.

**Keep sorafenib tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of sorafenib tablets**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use sorafenib tablets for a condition for which it is not prescribed.

Do not give sorafenib tablets to other people even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about sorafenib tablets that is written for health professionals.

**What are the ingredients in sorafenib tablets?**

**Active Ingredient:** Sorafenib tosylate, USP

**Inactive Ingredients:** croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, opadry 04F550007 Red. Opadry 04F550007 Red contains Hypromellose, titanium dioxide, polyethylene glycol and ferric oxide red.

For more information about sorafenib tablets call 1-800-912-9561

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This Patient Information has been approved by the U.S. Food and Drug Administration.