

Sorafenib

Nexavar®

Cancer-directed targeted therapy in tablets

Understanding your treatment

What is targeted therapy?

This treatment targets specific molecules, which are inside or on the surface of cancer cells. By targeting cancer cells, the targeted therapy limits damage to healthy cells. This type of treatment can be used alone or in combination with other treatments such as chemotherapy.

How can a targeted therapy help you?

Depending on your type of cancer and the stage of the disease, a targeted therapy can be used to :

- **Destroy** cancer cells
- **Stop** the cancer from spreading
- **Slow** the growth of cancer cells

How will you feel while on a targeted therapy?

Even though those treatments target cancer cells and limit damage to healthy cells, side effects can still arise.

Not everyone has side effects and each person's experience may differ. Side effects and their severity are not representative of the treatment's effect or lack thereof.

This document presents the most frequent side effects that your targeted therapy causes.

Medication

Sorafenib

Tablets to take by mouth

Administration

To be taken twice daily (approximately every 12 hours)

Take on an empty stomach : 1 hour before a meal or 2 hours after.

On a continuous basis



A **blood test** will be done throughout your treatment cycle. Depending on the results and side effects of the previous treatment, the dose of the medication might be adjusted or the treatment might be delayed.

How to take your medication?

- Take your sorafenib tablets as prescribed twice daily approximately every 12 hours. You should take your tablets on an empty stomach (1 hour before or 2 hours after a meal) with a large glass of water.
- Tablets must be taken whole. Do not chew, split or crush the tablets.
- If you forget a dose, you may take it as soon as you remember but do not double your next dose. Try, however, to take your tablets at the same time every day and in the same way (on an empty stomach).

Storing and handling your medicines



- Wash your hands immediately after handling your tablets.
- Keep your medication at room temperature, out of the reach of children and pets as well as protected from light, heat or moisture. Do not keep medicines in the bathroom.
- Don't throw away unused medication at home. Bring it back to your pharmacy to be destroyed safely. You may dispose of the empty containers in your home garbage can.
- Pour the pills from the container into the cap to avoid contact with other surfaces. If it inadvertently comes in contact with the surrounding surface, wash and rub the surface with water and soap.
- Caregivers should wear disposable gloves if they prepare medication for you. You can find disposable gloves at your local community pharmacy.
- Keep your medications in their original container and do not mix them with other drugs. The container should never be reused to put other objects or food.

How can this treatment affect your daily life?

Appetite

- Your **appetite may diminish**. Eat more often, in smaller quantities.
- Your **sense of taste may be altered**. Enhance foods with *fines herbes* or lemon juice. Eating fruits and unsweetened candies, chewing non-sugared gums, etc., may mask the metallic taste.
- **Alcohol** in small quantities is allowed and will not affect the efficacy of the treatments.



Sex life and birth control



- You can have an **active sexual** life during your treatments. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress, etc.).
- It's safe to kiss, to touch, to hold hands, to sleep in the same bed and to cuddle.
- The effect of the drug on male or female fertility is unknown. This medication may have an effect on the menstrual cycle as well as spermatozoid production. However, this does not prevent erection or sexual activity and as such, you can have an active sexual life during your treatments. Pregnancy is possible and this medication could be harmful to the fetus. The use of an effective method of contraception is highly recommended for both men and women during treatments and up to 2 weeks after the end of the treatments. Breast-feeding is contraindicated during treatment.

Foods and medicines to avoid



- **Grapefruit**
You must avoid consuming grapefruit, Seville orange, starfruit, pomelo, pomegranate or foods containing them. The consumption of those foods could increase the side effects of sorafenib.

Tips and precautions



- **Sit down to urinate and fold down the toilet lid**
Women as well as men should sit down to urinate and fold down the toilet lid before flushing in order to avoid splashing. Flush twice to make sure everything has been flushed away. Follow these precautions during your treatments (or according to instructions from your cancer center).
- **Bodily fluids**
During the treatment period, it's possible that a certain quantity of the medication is found in some bodily fluids or secretions that you produce, such as urine, stools, vomit, sperm and vaginal discharge. In order to protect the environment and those living with you, follow the instructions given by your cancer center about the right way to handle and dispose of the bodily fluids.



- **Over the counter medicines, natural health products and vaccines**
Consult your healthcare team :
 - if you intend to take any other medication (with or without a prescription) or natural health products.
 - if you need to receive a vaccine.

This could decrease your treatment's efficacy or increase its side effects.

- **Always have on hand the complete list of your medications**
Be sure to always have on hand the complete list of your medications, dietary supplements, vitamins and other natural health products. Give it to you doctor and your pharmacist. It is important to make them aware of any change.
- Notify your dentist or physician that you are receiving sorafenib if you have to undergo **surgery**.

What are the side effects of your treatment?

This fact sheet aims to let you know the side effects most commonly seen following the administration of your treatment. Please note that when you take any medication, there is a possibility that it causes rare side effects and it is difficult to predict which patients will be affected.

ADVERSE EFFECTS

MANAGEMENT

Diarrhea

You may sometimes experience diarrhea, which may start during your treatment.

- Drink lots of liquids (8 to 10 glasses a day) unless otherwise instructed by your doctor.
- Eat and drink often but in small quantities.
- ✔ **Continue your treatment if:** you have light diarrhea (2 to 3 additional loose stools per day compared to usual before starting your treatment). Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose stool for a maximum of 8 tablets per 24 hours period. Contact a member of your healthcare team if the diarrhea does not improve after taking loperamide for 24 hours.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you experience more than 4 to 6 additional loose stools per day compared to usual before starting your treatment. Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose stool for a maximum of 8 tablets per 24 hours period.
- ✖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have 7 or more additional loose stools per day compared to usual before starting your treatment, if you are not able to hold it in (incontinence) or if you have diarrhea with a fever.

Fatigue

Significant fatigue and weakness may occur during your treatments. This is usually temporary and may be related to different reasons (medication, stress, the disease).

- Maintain a good level of activity but rest when you feel the need to.

Hand and foot problems

Hand and foot syndrome may appear during your treatment. You may experience numbness, tingling, swelling, redness on the palms of your hands and underneath your feet. Pain, blisters, peeling of the skin may accompany these symptoms.

To prevent this syndrome :

- Avoid wearing tight clothes or shoes. Wear absorbent sponge rubber soles, and/or gel pads to relieve pressure points.
- Pat dry your hands and feet rather than rubbing them.
- Wear light clothing or keep skin free of clothing to avoid perspiring.

- Wear rubber gloves while washing dishes.
- Wash your hands and feet in lukewarm water; avoid hot water.
- Moisturize your skin regularly using a non-perfumed emollient and thick cream.
- Avoid activities that require applying pressure and repetitive friction on your hands and feet.

If symptoms occur:

- ✓ **Continue your treatment but contact your healthcare team if:** you have numbness, redness, or tingling on your hands and feet, but it's not painful.
- ⚠ **Stop your treatment and call your healthcare team as soon as possible if:** you have redness, swelling or peeling of the skin with pain to the hands and feet, but it does not prevent you from doing your daily activities.
- ✗ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have redness, swelling and lesions (ulcers) to the hands and feet with pain, and if it prevents you from doing your daily activities.

Skin problems

You might experience some **skin reactions** after starting your treatment :

- You might develop a **rash** on the face, neck, chest, back, and arms. This reaction looks like acne and usually disappears within a few weeks after the end of the treatment.
- Your **skin** may become **drier**. Redness and itchiness may develop.
- Your skin may become more **sensitive to the sun**.

To help prevent or decrease these reactions:

- Use fragrance-free, alcohol-free mild soap or cleaning products. Also use bath or shower oils to avoid skin dryness.
- Moisturize your skin twice a day with fragrance-free, thick, emollient-based creams like Aveeno^{MD}, Neutrogena^{MD} or Vaseline Intensive Care^{MD} lotion.
- Use non perfumed creams and cosmetics without alcohol or dye. Use dermatologist-recommended make up (foundation) to mask skin problems.
- Remove make up with a mild cleaning product.
- Avoid sun exposure. In case of unavoidable sun exposure, wear a hat and clothes with long sleeves.
- Avoid over the counter acne care that can dry the skin.
- Use a broad-spectrum sunscreen (SPF of 30 or more).

If despite all these measures, skin reactions appear:

- ✓ **Continue your treatment but contact your healthcare team if :** you develop skin problems such as pimples or

redness, scattered on your skin but that are not itchy or tender. Continue to apply moisturizing cream.

- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you develop skin problems such as pimples or redness, scattered on your skin and they itch or are tender. Continue to apply moisturizing cream.
- ⊘ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** if you develop skin problems, such as pimples or redness all over your body, pain or swelling.

Nausea

Rarely, slight nausea may occur during your treatment.

- You will be prescribed medication to be taken as needed if you have nausea.

High blood pressure

High blood pressure might occur.

- Your blood pressure might be checked during your visit with your doctor.
 - A member of your healthcare team might ask you to measure your blood pressure regularly and record it in a diary.
 - If you experience high blood pressure, medication can be prescribed to control it.
 - ✔ **Continue your treatment if:** your resting blood pressure is below 140/90 mmHg.
 - ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** your blood pressure is above 140/90 mmHg over a short period of time or less than 24 hours.
 - ⊘ **Stop your treatment and call your healthcare team as quickly as possible if:** your blood pressure is above 160/100 mmHg all or most of the time over a period of 24 hours. **Head to the Emergency Room** if your blood pressure is above 200/120 mmHg or if you have a headache or are confused.
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ADVERSE EFFECTS

MANAGEMENT

Decrease in white blood cells

A decrease in the **white blood cells** is unlikely during your treatment.

Nevertheless, you could be at higher risk to contract infections during this period.

- Wash your hands often.
- Avoid coming in contact with people who have contagious diseases.
- Contact a member of your healthcare team quickly if you notice any signs of infection (chills, cough, sore throat, pain while you urinate, etc.)
- In case of fever, do not take acetaminophen (Ex: Tylenol®, Atasol®) and anti-inflammatory medication (Ex: Motrin®, Advil®, Aleve®).

⊖ Stop your treatment and go to the Emergency Room if:

- you have a fever of 38,3 °C (101°F) or above
or
- you have a fever of 38 °C (100,4°F) twice an hour apart.

Minor bleeding

Minor bleeding such as nose bleeds may occur.

If a nosebleed occurs:

- Sit down straight with your head slightly bent forward.
- Apply a continuous pressure on your nostrils for a few minutes then check if the bleeding has stopped.
- Avoid blowing your nose for 12 hours after the bleeding episode.

⊖ Stop your treatment and call your healthcare team or go to the Emergency Room if: you have prolonged bleeding (more than 20 minutes), or if it's not possible to stop it, or if you have blood in your stools or urine or if you cough up blood.

Hair loss

Depending on the individual, **thinning of the hair** may occur. In general, this happens 2 to 3 weeks after the start of the treatment. However, don't worry; your hair will grow back after treatments have ended.

- Use gentle shampoo.
- In order to slow hair loss, avoid brushing hair vigorously.
- Avoid hair spray, dyes and perms.



RARE ADVERSE EFFECTS THAT CAN BE SEVERE OR SERIOUS

If the following side effects occur, stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room:

- If you have significant abdominal pain with nausea, vomiting and diarrhea or constipation

PHARMACIST : _____

PHONE : _____

FROM ____ H____ TO ____ H____ (MONDAY TO FRIDAY)

This fact sheet has been prepared by a sub-committee of the Comité national de l'évolution de la pratique des soins pharmaceutiques of the Programme québécois de cancérologie of the Ministry of Health and Social Services in consultation with the Comité de l'évolution de la pratique en oncologie of the Institut national d'excellence en santé et en services sociaux.

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Treatment Diary | Sorafenib

CYCLE START DATE :

LEGEND

- ✔ Continue your treatment.
- ⚠ Continue your treatment (*except hand and foot problems: stop) and contact your healthcare team as soon as possible.
- ❌ Stop your treatment and contact your healthcare team without delay or go to the Emergency Room.

Refer to the information sheet for more details

TREATMENT

(Record the dose taken)

Morning **200 mg**

Evening **200 mg**

Date (dd-mm)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28

DIARRHEA	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
✔ Light diarrhea: you have 2 to 3 additional loose stools per day compared to usual.																												
⚠ Moderate diarrhea: you have 4 to 6 additional loose stools per day compared to usual.																												
❌ Severe diarrhea: you have 7 or more additional loose stools per day compared to usual before starting your treatment or you are not able to hold it in (incontinence).																												
HAND AND FOOT PROBLEMS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
✔ Numbness, redness, or tingling on your hands and feet, but it's not painful.																												
⚠ Redness, swelling or peeling of the skin with pain to the hands and feet, but it does not prevent you from doing your daily activities.																												

