Medication Information Sheet

SORAfenib (sor-a-FEN-ib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Nexavar®

Appearance: tablet

What is this medication for?

• For treating certain types of leukemia and cancers which start in the liver, kidney or thyroid

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), especially if you:

- have / had high blood pressure,
- have / had blood clots or blockages of arteries (including stroke),
- have / had irregular heartbeat,
- will be undergoing major surgery or dental work,
- are taking blood thinners,
- have any allergies.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the <u>Hepatitis B and Cancer Medications</u> pamphlet for more information.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is any chance of pregnancy happening, you and your partner together must use 2
 effective forms of birth control at the same time until at least 2 weeks after your last dose.
 Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication.

How is this medication given?

- This medication is usually taken twice a day by mouth. Talk to your health care team about how and when to take your medication.
- Swallow whole with a glass of water on an empty stomach, at least one hour before or two hours after food. You may also take this medication with a low-fat meal.
- Take the doses at about the same times each day.
- Do not crush, chew, or split the tablets.
- If you vomit (throw up) after taking your medication, talk to your health care team about what to do.
- If you forget to take a dose of your medication do not take extra (double up). Follow the
 instructions given to you or talk to your health care team if you are unsure about what to do. If you
 are unable to talk to your healthcare team, take your next dose at the usual time.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

What else do I need to know while on this medication?

- Will this medication interact with other medications or natural health products?
 - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
 - Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
 - Check with your health care team before starting or stopping any of them.
- If you are taking a blood thinner (such as warfarin), your health care team may need extra blood tests and may change your dose.
- What should I do if I feel unwell, have pain, a headache or a fever?
 - **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time

OR

■ 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.
- Ask your health care team for the <u>Fever</u> pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- Talk to your health care team before you start taking <code>lbuprofen</code> (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take low dose aspirin for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures. Your wounds may take longer to heal or may not fully heal.
- DO talk to your health care team about your risk of getting other cancers after this treatment.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- DO NOT eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of drug in your blood and increase side effects.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.
- What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

 Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting sorafenib. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on sorafenib.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Too much or too little salt in your body	Get emergency medical help right
(May be severe) What to look for?	away for severe symptoms.
 Muscle spasms, cramping, weakness, twitching, or convulsions. Irregular heartbeat, confusion or blood pressure changes. 	
What to do?	
Get emergency medical help right away for severe symptoms.	
Low neutrophils (white blood cells) in the blood (neutropenia)	If you have a fever, try to contact your
(May be severe)	health care team.
When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.	If you are unable to talk to the team for advice, you MUST get emergency medical help right
What to look for?	away.
 If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). Do not eat or drink anything hot or cold right before taking your temperature. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
You have a fever if your temperature taken in your mouth (oral temperature) is:	
38.3°C (100.9°F) or higher at any time OR	
• 38.0°C (100.4°F) or higher for at least one hour.	
What to do?	
If your health care team has told you that you have low neutrophils:	
 Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 	
If you have a fever:	
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.	
Unusual bruising or bleeding	Talk to your health care team if you
(May be severe) What to look for?	have any signs of bleeding. If you have bleeding that
Watch for signs of bleeding:	doesn't stop or is severe (very
 bleeding from your gums unusual or heavy nosebleeds bruising easily or more than normal black coloured stools (poo) or blood in your stools (poo) coughing up red or brown coloured mucus dizziness, constant headache or changes in your vision heavy vaginal bleeding red or pink coloured urine (pee) 	heavy), you MUST get emergency help right away.
What to do?	
 Check with your healthcare team before you go to the dentist or if you have a surgery planned. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 Take care of your mouth and use a soft toothbrush. Try to prevent cuts and bruises. Ask your health care team what activities are safe for you. 	
If you have signs of bleeding:	
If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes.	
If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.	
Diarrhea	Talk to your health care team if no
What to look for?	improvement after
Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. What is 3.2.	24 hours of taking diarrhea medication or if severe (more than 7 times in one
What to do?	day).
If you have diarrhea:	
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. Ask your health care team for the Diarrhea pamphlet for more information. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Higher than normal levels of pancreas enzymes in your blood (lipase, amylase)	Talk to your health care team if you have any symptoms. If you are unable to talk
(May be severe)	
What to look for?	to the team for
 These changes usually do not cause any symptoms. In some cases, you may feel pain in the centre of your belly that may spread to your back. 	advice, you must get emergency medical help right away.
What to do?	
Your health care team may do blood tests to watch your levels of enzymes in the pancreas.	
Talk to your health care team if you have any symptom. If you are unable to talk to the team for advice, you must get emergency medical help right away.	
Rash; dry, itchy skin	Talk to your health
(May be severe)	care team if it does not improve
What to look for?	or if it is severe.
 You may have cracked, rough, flaking or peeling areas of the skin. Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. The rash may be seen in areas where you have had radiation before. 	
What to do?	
To prevent and treat dry skin:	
 Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. 	
Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Fatigue What to look for? • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep.	Talk to your health care team if it does not improve or if it is severe.
What to do?	
 Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Ask family or friends to help you with things like housework, shopping, and child or pet care. Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. Ask your health care team for the Fatigue pamphlet for more information.	
Liver problems	Get emergency
(May be severe)	medical help right away.
Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.	
What to look for?	
Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe.	
What to do?	
If you have any symptoms of liver problems, get emergency medical help right away.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Rash on your hands and feet (hand-foot syndrome) What to look for?	Talk to your health care team if it does not improve or if it is severe.
 Tingling or swelling of the skin on the palms of your hands and the bottoms of your feet. This can become painful, red and numb. In worse cases your skin may start to peel and you can get blisters or sores. This may happen days or weeks after you start treatment. 	
What to do?	
To help prevent Hand-foot syndrome:	
 Do not do activities that cause rubbing or pressure on your skin, like heavy-duty washing, gripping tools, typing, playing musical instruments, and driving. Moisturize your hands and feet often, especially in the skin folds. Wear loose, comfortable footwear and clothes. Rest and try to keep off your feet. Do not let your hands and feet get too hot. 	
Ask your health care team for the <u>Hand-foot syndrome</u> pamphlet for more information.	
Hair thinning or loss What to look for?	Talk to your health care team if this bothers you.
 Your hair may begin to become thin or fall out during or after treatment. In most cases, your hair will grow back after treatment, but the texture or colour may change. In very rare cases, hair loss may be permanent. 	
What to do?	
 Use a gentle soft brush. Do not use hair sprays, bleaches, dyes and perms. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Nausea and vomiting	Talk to your
(Generally mild)	healthcare team if nausea lasts more than 48 hours or
What to look for?	vomiting lasts
 Nausea is feeling like you need to throw up. You may also feel light- headed. 	more than 24 hours or if it is severe.
You may feel nausea within hours to days after your treatment.	
What to do?	
To help prevent nausea:	
 It is easier to prevent nausea than to treat it once it happens. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (like coffee, tea) and avoid alcohol. 	
If you have nausea or vomiting:	
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the <u>Nausea & Vomiting</u> pamphlet for more information. Talk to your health care team if: 	
 nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe 	
High blood pressure	Talk to your health
(May be severe)	care team if it does not improve or if it is severe.
What to look for?	
 There are usually no signs of high blood pressure. Rarely, you may have headaches, shortness of breath or nosebleeds. 	
What to do?	
 Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
If you have a severe headache, get emergency help right away as it may be a sign your blood pressure is too high.	
Low appetite	Talk to your health
What to look for?	care team if it does not improve or if it is severe.
Loss of interest in food or not feeling hungry.Weight loss.	of it it is severe.
What to do?	
 Try to eat your favourite foods. Eat small meals throughout the day. You may need to take meal supplements to help keep your weight up. Talk to your health care team if you have no appetite. 	
Ask your health care team for the <u>Loss of Appetite</u> pamphlet for more information.	
 Constipation What to look for? Having bowel movements (going poo) less often than normal. Small hard stools (poo) that look like pellets. The need to push hard and strain to have any stool (poo) come out. Stomach ache or cramps. A bloated belly, feeling of fullness, or discomfort. Leaking of watery stools (poo). Lots of gas or burping. Nausea or vomiting. 	Talk to your health care team if it does not improve or if it is severe.
What to do?	
To help prevent constipation:	
 Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. Be Active. Exercise can help to keep you regular. If you take opioid pain medication, ask your health care team if eating more fibre is right for you. 	

Side effects and what to do	When to contact health care team
To help treat constipation: • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. Ask your health care team for the Constipation Pamphlet for more information. Cough and feeling short of breath What to look for? • You may have a cough and feel short of breath. • Symptoms that commonly occur with a cough are: • Wheezing or a whistling breathing • Runny nose • Sore throat • Heartburn • Weight loss • Fever and chills • Rarely this may be severe with chest pain, trouble breathing or coughing up blood.	Talk to your health care team. If you are not able to talk to your health care team for advice, and you have a fever or severe symptoms, you MUST get emergency medical help right away.
 Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?". If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
 Tingling or numb feeling on the skin What to look for? Numbness or tingling that most often happens in your hands, arms, legs or feet but can happen elsewhere in the body as well. It can sometimes be painful and feel like burning, which may be severe. 	Talk to your health care team, especially if you have trouble doing tasks like doing up buttons, writing, moving, or if you have severe pain

When to contact health care team
or numbness.
Talk to your health care team if it
does not improve or if it is severe.
Talk to your health
care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow.

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
If you have mouth sores:	
 Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. 	
Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.	
Headache; mild joint, muscle pain or cramps What to look for?	Talk to your health care team if it does not improve or if it is severe.
 Mild headache New pain in your muscles or joints, muscle cramps, or feeling achy. 	
What to do?	
 Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. Rest often and try light exercise (such as walking) as it may help. 	
Ask your health care team for the Pain pamphlet for more information.	

Other rare, but serious side effects are possible. If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Pain, swelling and hardening of the vein in an arm or leg
- Severe headache, confusion, seizures
- Sudden loss of vision, trouble speaking or moving your arms or legs
- Chest pain, irregular heartbeat, fainting spells or pain in your belly or arm
- Extreme tiredness that prevents you from exercising or doing normal activities
- Swelling in your legs, ankles and belly, having little or no pee
- Weakness of one side of your body

- Sudden severe pain in your upper back, that moves up your neck or down your back, when you didn't hurt yourself
- Severe itchiness, rash, swollen lips, face or tongue, chest and throat tightness
- A rash that look like small bruises, purplish-red spots/patches on your skin
- Unusual hoarse or raspy voice
- Unusual pulsating for throbbing feeling in your chest or belly
- Severe belly pain and changes in your bowel movements, trouble swallowing
- · Severe muscle pain or weakness, dark-coloured pee
- Unusual pus discharge from gums, loosening of teeth and the feeling of numbness or heaviness in the jaw
- Signs of an overactive thyroid such as unusual weight loss, feeling anxious, irritable or having trouble sleeping, sweating a lot and having trouble dealing with hot weather, fast or uneven heartbeats
- Signs of an underactive thyroid such as unusual weight gain, getting cold easily, a lack of energy or feeling tired, dry skin, nails or hair that breaks easily

Who do I contact if I have questions or need help?
My cancer health care provider is:
During the day I should contact:
Evenings, weekends and holidays:
Other Notes:

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

March 2023 Modified "What should I do before I have this medication" section

SORAfenib

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.