

For the Patient: **GISORAF**

Other Names: Therapy for Advanced Hepatocellular Carcinoma Using Sorafenib (NEVAXAR®)

GI = GastroIntestinal SORAF = Sorafenib

ABOUT THIS MEDICATION

What is this drug used for?

- Sorafenib (so-RA-fe-nib) is an oral drug treatment given as therapy to treat a type of advanced liver cancer (hepatocellular carcinoma).
- How do these drugs work?
- Sorafenib works by interfering with certain enzymes called tyrosine kinases that play a role in how cells grow, and also helps prevent the growth of new blood vessels from surrounding tissue to a cancer. By doing so, sorafenib helps prevent an increase in the number of cancer cells.

INTENDED BENEFITS

- This drug is being given to destroy and/or limit the growth of cancer cells in your body. This
 treatment may improve your current symptoms, and delay or prevent the onset of new
 symptoms.
- It may take several treatments before your doctor can judge whether or not this medicine is helping.

TREATMENT SUMMARY

How are these drugs given?

- This medication is usually given as one dose twice a day. Sometimes, sorafenib may be given at a lower dose, once daily, or every other day.
- Sorafenib is a tablet which is taken by mouth.

What will happen when I get my drugs?

- A blood test is done on a regular basis, to monitor the effects of the drug on your body. The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.
- The doctor will review the results of the blood test and meet with you each cycle. If you are to proceed with treatment, the appointment would usually be scheduled for the following day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

You doctor will review the risks of treatment and possible side effects with you before starting treatment. The pharmacist will review how to take sorafenib and possible side effects with you on the day you first pick up your medication.

SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Hand-foot skin reaction may sometimes occur during sorafenib treatment. The palms of your hands and soles of your feet may tingle, become red, numb, painful, or swollen. Skin may also become dry or itchy. You may not be able to do your normal daily activities if blisters, severe pain, or ulcers occur.	 Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as that caused by heavy activity. Avoid tight-fitting jewellery. Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. Apply lanolin-containing creams (e.g., BAG BALM®, UDDERLY SMOOTH®) to hands and feet, liberally and often. Tell your cancer doctor or your nurse at the next visit if you have any signs of hand-foot skin reaction as your dose may need to be changed
Your white blood cells may decrease during your treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	 To help prevent infection: Wash your hands often and always after using the bathroom. Avoid crowds and people who are sick. Stop taking sorafenib and call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.
Your platelets may decrease during your treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual .	 To help prevent bleeding problems: Try not to bruise, cut, or burn yourself. Clean your nose by blowing gently. Do not pick your nose. Avoid constipation. Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding. Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable.

OTHER SIDE EFFECTS	MANAGEMENT
DURING TREATMENT	
Skin rashes, dryness or itching may sometimes occur.	 Wear loose cotton clothes. Urea-containing lotions may be helpful, particularly if the skin is very dry (e.g., UREMOL®, URISEC®) If very irritating, call your doctor. Otherwise, make sure to mention it at your next visit.
Diarrhea may sometimes occur.	If diarrhea is a problem:
	 Drink plenty of fluids.
	 Eat and drink often in small amounts.
	Avoid high fibre foods as outlined in <i>Food</i> Ideas to Help Manage Diarrhea*
Constipation may sometimes occur.	• Exercise if you can.
	 Drink plenty of fluids.
	Try ideas in Food Choices to Manage Constipation.*
Nausea does not usually occur with sorafenib.	
Headache or pain may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Tiredness and lack of energy may sometimes occur.	 Do not drive a car or operate machinery if you are feeling tired.
	 Try the ideas the handout titled Fatigue/Tiredness*
Hair loss sometimes occurs with sorafenib.	• Use a gentle shampoo and soft brush.
	 Care should be taken with use of hair spray, bleaches, dyes, and perms.
Numbness or tingling of the fingers or toes may sometimes occur.	 Be careful when handling items that are sharp, hot or cold.
	 Tell your doctor at your next visit, especially if you have trouble with buttons, writing, or picking up small objects.
High blood pressure may sometimes occur. This can happen very quickly after starting	Your blood pressure will be checked during your visits to your doctor.
treatment.	 You may be asked to check your blood pressure frequently between visits.
	 Your doctor may give you medication if your blood pressure is high.
	 Tell your doctor if you are already on blood pressure medication. Your doctor may have to adjust your dose.
*Please ask your chemotherapy nurse, pha	

*Please ask your chemotherapy nurse, pharmacist, or dietitian for a copy

INSTRUCTIONS FOR THE PATIENT

- It is important that you measure your blood pressure frequently at home, in particular in the beginning of your treatment (especially in the first 2 cycles of therapy). Keep a journal of your daily measured blood pressure to submit to your physician with your next visit. Sometimes sorafenib can cause increased blood pressure very quickly after initiation of therapy.
- It is important to **take** sorafenib exactly as directed by your doctor. Make sure you understand the directions.
- **Take** sorafenib on an **empty** stomach. If you get nauseated from taking it on an empty stomach, try a small **low-fat** meal with it.
- If you **miss a dose** of sorafenib, take it as soon as you can if it is within 6 hours of the missed dose. If it is over 6 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- If you **vomit** the dose of sorafenib within 30 minutes of taking it, repeat the dose. Let your doctor know as a medication to prevent nausea may be required for future doses.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of sorafenib.
- It is not known if sorafenib causes **sterility** in men or **menopause** in women. If you plan to have children, discuss this with your doctor before being treated with sorafenib.
- Sorafenib may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with sorafenib. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Store sorafenib tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- **Tell** doctors, dentists, and other health professionals that you are being treated with sorafenib before you receive any treatment from them.
- If you are planning to have **major surgery** (e.g., joint replacement), tell your surgeon that you are taking sorafenib. You may need to stop taking sorafenib at least 2 weeks prior to surgery. Restart it only after your doctor says your wounds have healed.

Medication Interactions

Other drugs such as warfarin (COUMADIN®) may **interact** with sorafenib. Tell your doctor if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed.

Check with your doctor or pharmacist before you start taking any new drugs

THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING SORAFENIB AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain, or shortness of breath.

• Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of ankles, or fainting.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Numbness or tingling in feet or hands.
- Skin rash or itching.
- Signs of **anemia** such as unusual tiredness or weakness.
- Headache or pain not controlled with acetaminophen (TYLENOL®).

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Easy bruising or minor bleeding.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Skin rash or itching.
- Impotence (loss of sexual ability)
- Weight loss or trouble eating.

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact:

at telephone number: