

## Medication Information Sheet

**regorafenib** (RE-goe-RAF-e-nib)

*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:** Stivarga®

**Appearance:** tablet

**What is this medication for?**

For treating colorectal cancer, gastrointestinal stromal tumours (GIST) or liver cancer in patients who have received treatment(s) before.

**What should I do before I have this medication?**

- Tell your doctor and pharmacist if you have or had significant medical condition(s), such as:
  - ◊ heart problems (including heart rhythm),
  - ◊ high blood pressure,
  - ◊ liver or kidney problems,
  - ◊ bleeding problems,
  - ◊ recent or upcoming surgery,
  - ◊ taking blood thinners or
  - ◊ have any allergies.
- People with cancer have a higher risk of getting other cancers or developing blood clots. Some cancer medications may increase these risks, especially if used for a long period of time. Discuss any concerns about this medication with your health care team.

**How will this medication affect sex, pregnancy and breastfeeding?**

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, become(s) pregnant during treatment, or if you are breastfeeding.
- If there is ANY chance that you or your partner may become pregnant, you and your partner together must:
  - ◊ ► Use 2 different forms of birth control while on treatment and for at least **8 weeks** after the last dose.

- Do not breastfeed while taking this drug.
- This medication may affect fertility (ability to get pregnant).

## How is this medication given?

- Regorafenib is usually taken by mouth daily for 21 days, followed by 7 days of rest (3 weeks on, 1 week off).
- Take regorafenib exactly how your doctor told you to take it.
- Swallow tablets whole with a glass of water, after a low-fat and low-calorie (300-550 calorie) meal. Example meal: 2 slices of white toast with 1 tablespoon of low-fat margarine, 1 tablespoon of jelly and one glass (8 ounces) of skim milk.
- A missed dose should be taken as soon as remembered on the same day. Otherwise, skip this and take the next dose on the following day. Do not take two doses on the same day.

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

- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. They may increase side effects.
- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements), such as antibiotics, antifungals, seizure medications and St. John's Wort. Check with your health care team before starting or stopping any of them.
- For mild aches and pain:
  - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
  - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding.
  - Talk to your health care team before you start or stop these medications.
  - If you feel unwell, take your temperature before taking any of these medications. They may hide a fever.
  - **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

## 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.
- Keep the desiccant in the bottle after the first opening. Keep the bottle tightly closed. Do not eat the desiccant.
- The tablets can be used for up to 7 weeks after the bottle has been opened.

## What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
<b>Very Common Side Effects (50 or more out of 100 people)</b>	
<b>Abnormal liver lab tests (may be severe)</b> <ul style="list-style-type: none"> <li>• You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens.</li> <li>• Your doctor may monitor your liver regularly with a blood test.</li> </ul>	Contact your health care team if no improvement or if severe
<b>Fatigue (tiredness)</b> <ul style="list-style-type: none"> <li>• Be active and 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.</li> <li>• Pace yourself, do not rush. Put off less important activities. Rest when you need to.</li> <li>• Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less).</li> <li>• Avoid driving or using machinery if you are feeling tired</li> </ul> <p>See our <a href="#">Fatigue</a> pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<b>Salt imbalances</b> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>	Get emergency medical help right away

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
<p><b>Low appetite</b></p> <ul style="list-style-type: none"> <li>You may not feel like eating or you may lose weight.</li> <li>Try to eat foods that you like and eat small meals throughout the day.</li> <li>You may need to take meal supplements to help keep your weight up.</li> <li>Talk to your health care team if you have a low appetite.</li> <li>See our <a href="#">Loss of appetite</a> pamphlet for more information.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Hand-foot syndrome (may be severe)</b></p> <p>You may have pain, thinning, reddening, tingling, numbness and peeling of the skin on your palms or the soles of your feet.</p> <p>This may occur days to weeks after the dose is given or after you start treatment.</p> <p><b>To help prevent Hand-foot syndrome :</b></p> <ul style="list-style-type: none"> <li>Avoid activities that cause rubbing, pressure or heat exposure to hands and feet (i.e. gripping tools, vigorous washing and hot baths).</li> <li>Apply moisturizer often to your hands and feet, especially in the skin folds.</li> <li>Wear loose, comfortable footwear and clothes. Rest and try to keep off your feet.</li> </ul> <p>Also see <a href="#">Hand-Foot Syndrome</a> pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<p><b>Abnormal levels of pancreas tests (lipase, amylase)</b></p> <p>Your doctor may monitor these regularly.</p>	Contact your health care team if no improvement or if severe
<p><b>Diarrhea</b></p> <p>May happen days to weeks after you get your treatment.</p> <p><b>If you have diarrhea :</b></p> <ul style="list-style-type: none"> <li>Take anti-diarrhea medication if your health care team prescribed it.</li> <li>Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol.</li> <li>Eat many small meals and snacks instead of 2 or 3 large meals.</li> <li>Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy.</li> </ul>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
See the <a href="#">Diarrhea</a> pamphlet for more information.	
<p><b>Fever, chills, infection</b></p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> <li>• <b>38.3°C (100.9°F) or higher at any time OR</b></li> <li>• <b>38.0°C (or 100.4°F) or higher for at least one hour.</b></li> </ul> <p>While you are getting treatment:</p> <ul style="list-style-type: none"> <li>• Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills).</li> <li>• Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever.</li> <li>• Do not eat or drink anything hot or cold right before taking your temperature.</li> <li>• Wash your hands often.</li> <li>• Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist.</li> </ul> <p><b>If you have a fever, talk to your health care team or go to the closest emergency room.</b></p> <p>See our <a href="#">Neutropenia (Low white blood cell count)</a> pamphlet for more information.</p>	Get emergency medical help right away
<b>Hoarseness (raspy voice)</b>	Contact your health care team if no improvement or if severe
<p><b>High blood pressure (may be severe)</b></p> <ul style="list-style-type: none"> <li>• Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure.</li> <li>• If you have a severe headache, severe dizziness, or if you faint get emergency help right away as it may be a sign your blood pressure is too high or too low.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Rash; dry, itchy skin</b></p> <p>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.</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
<p><b>To prevent and treat dry skin,</b></p> <ul style="list-style-type: none"> <li>• Use skin moisturizer.</li> <li>• Protect your skin from the sun and the cold.</li> <li>• Use sunscreen with UVA and UVB protection and a SPF of at least 30.</li> </ul>	

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<p><b>Mouth sores</b></p> <p>You may have round, painful, white or gray sores inside your mouth. They can occur on the tongue, lips, gums, or inside your cheeks. In more severe cases they may make it hard to swallow, eat or to brush your teeth. They usually last 1 to 2 weeks.</p> <p>To help prevent mouth sores:</p> <ul style="list-style-type: none"> <li>• Take care of your mouth by gently brushing and flossing regularly.</li> <li>• Rinse your mouth often. Do not use mouthwashes with alcohol.</li> <li>• Instead, try a homemade mouthwash:</li> <li>• Mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water.</li> </ul> <p>If you have mouth sores:</p> <ul style="list-style-type: none"> <li>• Check with your health care team as soon as you notice mouth or lip sores or if it hurts to swallow.</li> <li>• Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a mouthwash to relieve mouth sores and prevent infection.</li> </ul> <p>See the <a href="#">Mouth Care</a> pamphlet for more information.</p>	<p>Contact your health care team as soon as possible</p>
<p><b>Headache; mild joint, muscle pain or stiffness</b></p> <ul style="list-style-type: none"> <li>• Take your pain medication as prescribed by your doctor.</li> <li>• You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<ul style="list-style-type: none"> <li>• Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medications may increase bleeding risk.</li> <li>• Rest often and try light exercise as it may help.</li> </ul>	

**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:**

- new cough, difficulty breathing, or coughing up blood
- chest pain and/or swelling of arms or legs
- sudden severe pain in your upper back, that moves up your neck or down your back, when you didn't hurt yourself
- weakness on one side of your body
- trouble speaking, seeing, swallowing or difficulty using your arms or legs
- irregular heartbeat and/or fainting spells
- severe headache, confusion, changes in your vision or seizures
- severe belly pain, sudden changes in your bowel movements or digestion
- unusual pulsating or throbbing feeling in your chest or belly
- peeing much less than usual, unusual weight gain
- new growths on your skin
- wounds that have trouble healing or do not heal well

**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:**

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**October 2020** Updated rare side effects section

For more links on how to manage your symptoms go to [www.cancercareontario.ca/symptoms](http://www.cancercareontario.ca/symptoms).

*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.*