

#### **Patient Information Leaflet**

# Regorafenib – STIVARGA®

### What is STIVARGA®

Medicine Name	Description
	40 mg pill: pink, oval
Regorafenib	BAYER 4'8

#### How should you take your medicine?

Your doctor has determined your medicine dosage.

In your case, the dosage is as follows:.....mg/day, i.e. ....40 mg pill(s) per day, once a day, for 21 days, every 28 days.

Swallow whole with a glass of water; do not crush, cut, chew, or dilute the pills.

At a set time, after a light meal (with a fat content of less than 30%)

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

## Dosage - therapy regimen

Once a day, at a set time, after a light meal	<b>\$</b> ⊝					<b>O</b> I	
From D1 to D21, resume on D29		 D1	D21	D22	D28		

## How to get the medicine supply?

This medicine is available in local pharmacies.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

## What else do you need to know?

#### Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts, coagulation parameters, ionogram, liver, thyroid, and pancreas function tests, albumin urine test), as well as clinical condition monitoring (arterial pressure, ECG).

#### Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).

#### Interactions with other medications and/or food

The occurrence of interactions between STIVARGA® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.

Example: While taking STIVARGA®, it is necessary to avoid using grapefruit and Saint John's wort.

## What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.

SIDE EFFECTS



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Most common ones	General: pain, fatigue, fever, infection
Most common ones	Skin problems: inflammation of palms, soles of the feet, and areas of friction, skin rash, dryness, hair loss Digestive problems: diarrhea, loss of appetite, taste perception disorder, inflammations inside the mouth (ulcers), nausea / vomiting, acid reflux Vascular problems: elevated arterial pressure, bleedings Abnormal lab results: abnormal liver function tests, low hemoglobin level (anemia), low platelet count (thrombocytopenia)
	Others: change of voice
WHEN TO ALERT THE MEDIC	
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	Hypertension symptoms  > Headaches, buzzing in the ears, and/or dizziness  > Blood pressure increase  Digestive problems  > Significant and/or rapid weight loss  > Very frequent diarrhea, bowel movement over 4 times a day  > Mouth pain or ulcers that prevent normal eating  > Severe abdominal pain  > Inability to drink for 24 hours and/or eat for about 48 hours  Symptoms suggestive of cardiac problems  > Shortness of breath, high palpitations, chest pain or tightness, sudden sweating, dizziness  Symptoms suggestive of infection  > Temperature > 38.5 °C  > Cough, throat pain, pain on urination, diarrhea with fever  Symptoms suggestive of hemorrhage  > Blood in stool or in vomit  > Hematomas (bruises), nose bleedings  Pain that prevents you from doing your normal activities  > Headaches  > Pain or inflammation in hands or feet  Symptoms suggestive of cerebral edema  > Headaches, confusion, convulsions, or vision problems
HOW TO PREVENT SIDE EFF	
Blood pressure control	Elevated blood pressure needs to be corrected. <b>Taking arterial pressure regularly</b> is recommended. Pharmacists can help you take your blood pressure. You can also ask to do it by yourself using an automatic blood pressure monitor.
Weight	Regularly check your weight in case of digestive problems.
Skin care	On hands and feet: Apply moisturizing cream or milk and/or healing cream on hands and feet (without rubbing hard).  Avoid exposing hands and feet to heat (hot water). Avoid activities that cause rubbing or injury.  Avoid wearing overly tight clothing, socks, or shoes  Body: Opt for soft soap and moisturizer, pat skin dry.  Avoid using any irritating products.  For sun protection, use broad spectrum sunscreen and avoid sun exposure.
Hair loss	Use a small amount of mild shampoo (for babies). Opt for a soft brush. Avoid washing your hair too often. Avoid heat sources (hairdryer, heated curlers, hot smoothing iron), dyes, highlights, or perm.
Oral hygiene	Use a soft toothbrush; use oral rinses containing baking soda.  Avoid oral rinses that contain menthol or alcohol.
Bleedings, hemmorhages	Avoid taking anti-inflammatory drugs (ibuprofen, aspirin)  Notify your doctor:  > if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed about surgical or dental intervention.
Infection	Avoid visiting high risk areas (crowds, contact with sick people,). A flu and pneumococcal infection vaccine might be recommended for you: it will protect you.
Fatigue	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports  Alternate periods of activity and rest.
HOW TO ADAPT YOUR DIET?	
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas.  Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol.  Drink more water.
Loss of appetite / taste perception disorders	Opt for a higher calorie diet and "pleasure diet". Opt for several small meals of warm and cold food per day. Avoid using metal kitchen utensils.
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes.  Limit consumption of fatty, fried, and spicy foods.
Inflammation inside mouth ulcers)	Avoid sour, sticky, or very salty foods.



(ulcers)