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Regorafenib

pronounced as (re" goe raf' e nib)

IMPORTANT WARNING:

Regorafenib may cause liver damage, which may be severe or life-threatening. Tell your doctor if you have or have ever had liver disease. If you experience any of the following symptoms, call your doctor immediately: yellowing of the skin or eyes, nausea, vomiting, dark colored urine, pain in the upper right part of the stomach, extreme tiredness, unusual bleeding or bruising, lack of energy, loss of appetite, flu-like symptoms, or a change in sleep habits.

Keep all appointments with the laboratory. Your doctor will order certain lab tests before and during your treatment to be sure that it is safe for you to take regorafenib and to check your body's response to the medication.

Why is this medication prescribed?

Regorafenib is used to treat colon and rectal cancer (cancer that begins in the large intestine or the rectum) that has spread to other parts of the body in people who have not been treated successfully with certain other medications. It is also used to treat gastrointestinal stromal tumors (GIST; a type of tumor that grows in the stomach, intestine [bowel], or esophagus [tube that connects the throat with the stomach]) in people who were not treated successfully with certain other medications. Regorafenib is also used to treat hepatocellular carcinoma (HCC; a type of liver cancer) in people who were previously treated with sorafenib (Nexafar). Regorafenib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps to slow or stop the spread of cancer cells.

How should this medicine be used?

Regorafenib comes as a tablet to take by mouth. It is usually taken with a low-fat meal (containing under 600 calories and less than 30% of calories from fat) once a day for 3 weeks and then skipped for 1 week. This treatment period is called a cycle, and the cycle may be repeated for as long as your doctor recommends. Take regorafenib at the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take

regorafenib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole; do not split, chew, or crush them.

Your doctor may decrease your dose of regorafenib or tell you to stop taking regorafenib for a period of time during your treatment. This will depend on how well the medication works for you and any side effects you may experience. Continue to take regorafenib even if you feel well. Do not stop taking regorafenib without talking to your doctor.

Regorafenib is not available at retail pharmacies. Your medication will be mailed to you or to your doctor from a specialty pharmacy. Ask your doctor if you have any questions about how you will receive your medication.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking regorafenib,

- tell your doctor and pharmacist if you are allergic to regorafenib, any other medications, or any of the ingredients in regorafenib tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements, you are taking or plan to take. Be sure to mention any of the following: anticoagulants ("blood thinners") such as warfarin (Coumadin, Jantoven); certain antifungal medications such as itraconazole (Onmel, Sporanox), ketoconazole (Nizoral), posaconazole (Noxafil), and voriconazole (Vfend); certain medications for seizures such as carbamazepine (Carbatrol, Eptitol, Tegretol), phenobarbital, and phenytoin (Dilantin, Phenytek); atorvastatin (Lipitor, in Caduet); clarithromycin (Biaxin, in Prevpac); fluvastatin (Lescol); irinotecan (Camptosar); methotrexate (Otrexup, Rasuvo, Trexall); rifampin (Rifadin, Rifamate, in Rifater); or telithromycin (Ketek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor what herbal products you are taking, especially St. John's wort. You should not take St. John's wort while taking regorafenib.
- tell your doctor if you have a wound that has not healed or if you have or have ever had bleeding problems, high blood pressure, chest pain, or heart, kidney or liver disease. Also tell your doctor if you recently had surgery.
- tell your doctor if you are pregnant or plan to become pregnant. If you are a female, you should not become pregnant while you are taking regorafenib and for up to 2 months after your final dose. Talk to your doctor about birth control methods that will work for you. If you are male, you and your female partner should use birth control during your treatment and continue to use birth control for 2 months after your final dose. If you or your partner become pregnant while taking regorafenib, call your doctor. Regorafenib may harm the fetus.
- tell your doctor if you are breast-feeding. You should not breastfeed during your treatment with regorafenib and for up to 2 weeks after your final dose.

- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking regorafenib. Your doctor probably will tell you to stop taking regorafenib at least 2 weeks before your surgery. Your doctor will tell you when it is safe for you to start taking regorafenib again after your surgery.

What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss a dose of regorafenib, take the missed dose as soon as you remember it on that day. Do not take two doses on the same day to make up for a missed one.

What side effects can this medication cause?

Regorafenib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- tiredness
- weakness
- loss of appetite
- diarrhea
- swelling, pain, and redness of the lining of your mouth or throat
- weight loss
- hoarseness or other change in the sound of your voice

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- chest pain
- shortness of breath
- unusual vaginal discharge or irritation
- burning or pain when urinating
- dizziness or feeling faint
- fever, cough, sore throat, chills, and other signs of infection
- swelling of the abdomen
- high fever
- chills
- severe diarrhea

- severe headache
- seizure
- confusion
- changes in vision
- dry mouth, muscle cramps, or decreased urination
- redness, pain, blisters, bleeding, or swelling on the palms of your hands or soles of your feet
- rash
- vomiting blood or vomiting material that looks like coffee grounds
- pink or brown urine
- red or black (tarry) stools
- coughing up blood or blood clots
- abnormally heavy menstrual bleeding (periods)
- unusual vaginal bleeding
- frequent nosebleeds

Regorafenib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Do not place the tablets in other containers, such as daily or weekly pill boxes, and do not remove the desiccant (drying agent) from the container. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Dispose of any unused tablets 7 weeks after the bottle is first opened.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps

and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- rash or other skin changes
- voice changes or hoarseness
- diarrhea
- swelling inside the nose or mouth
- dry mouth
- decreased appetite
- tiredness

What other information should I know?

Keep all appointments with your doctor. Your doctor will check your blood pressure before you begin taking regorafenib and regularly during your treatment.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Stivarga®

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