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Pazopanib

pronounced as (paz oh' pa nib)

IMPORTANT WARNING:

Pazopanib may cause severe or life-threatening liver damage. 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; dark urine; extreme tiredness; nausea; vomiting; loss of appetite; pain in the upper right part of the stomach; or unusual bleeding or bruising.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before you start taking pazopanib and at least once a month for the first 4 months of your treatment and then on a regular basis as needed.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with pazopanib and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking pazopanib.

Why is this medication prescribed?

Pazopanib is used to treat advanced renal cell carcinoma (RCC, a type of cancer that begins in the cells of the kidneys) in adults. Pazopanib is in a class of medications called kinase inhibitors. It works by slowing or stopping the spread of cancer cells.

How should this medicine be used?

Pazopanib comes as a tablet to take by mouth. It is usually taken on an empty stomach once a day, at least 1 hour before or 2 hours after a meal. Take pazopanib at around 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 pazopanib 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 adjust your dose of pazopanib during your treatment or may discontinue your treatment. This depends on how well the medication works for you and any side effects you may experience. Talk to your doctor about how you are feeling during your treatment. Continue to take pazopanib even if you feel well. Do not stop taking pazopanib without talking to your doctor.

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 pazopanib,

- tell your doctor and pharmacist if you are allergic to pazopanib, any other medications, or any of the ingredients in pazopanib tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: cisapride (Propulsid) (not available in the U.S.); clarithromycin (Biaxin, in Prevpac); dofetilide (Tikosyn); erythromycin (E.E.S., E-Mycin, Erythrocin); ketoconazole (Nizoral); certain medications for irregular heartbeat such as amiodarone (Cordarone), digoxin (Digitek, Lanoxicaps, Lanoxin), diltiazem (Cardizem, Dilacor, Tiazac, others), disopyramide (Norpace), flecainide (Tambocor), mexiletine (Mexitil), procainamide (Procanbid), propafenone (Rythmol), propranolol (Inderal, Innopran XL, in Inderide), quinidine, sotalol (Betapace, Betapace AF, Sorine), and verapamil (Calan, Isoptin, Verelan); moxifloxacin (Avelox); pimozide (Orap); rifampin (Rifadin, in Rifamate, in Rifater, Rimactane); ritonavir (Norvir, in Kaletra); sparfloxacin (Zagam) (not available in the U.S.); and thioridazine (Mellaril). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with pazopanib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you have coughed up blood or had bleeding in your stomach, intestines, or brain in the last 6 months or had surgery in the last 7 days. Also tell your doctor if you have or have ever had a tear in your stomach or intestine; an abnormal connection between two parts of your gastrointestinal tract; Gilbert's syndrome (a genetic condition which affects the liver and may cause jaundice [yellowing of the skin or eyes]); high blood pressure; a stroke; an irregular heartbeat; a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death); a heart attack; chest pain; or heart or thyroid disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. You should not become pregnant while you are taking pazopanib. If you become pregnant while taking pazopanib, call your doctor. Pazopanib may harm the fetus.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking pazopanib.

What special dietary instructions should I follow?

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

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is within 12 hours of your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

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

- diarrhea
- constipation
- heartburn
- change in ability to taste food
- joint or muscle pain
- swelling of the face
- tender, red palms of the hands and soles of the feet
- hair loss
- thin, brittle fingernails or hair
- change in hair color
- lightening of an area of the skin
- rash
- weakness
- depression
- unusual discomfort in cold temperatures
- weight loss

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:

- fast or irregular heartbeat
- chest pain
- pain in the arms, back, neck or jaw
- shortness of breath
- headache
- slow or difficult speech

- dizziness or faintness
- weakness or numbness of an arm or leg
- wounds that do not heal
- stomach pain or swelling
- black and tarry stools
- red blood in stools
- bloody vomit
- vomit that looks like coffee grounds
- blood in urine
- nosebleeds
- coughing up blood

Pazopanib 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. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

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:

- extreme tiredness

What other information should I know?

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

- Votrient®

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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