

MEDICATION GUIDE

Pazopanib (paz oh' pa nib) Tablets

Medication Guide available at www1.apotex.com/products/us

What is the most important information I should know about pazopanib tablets?

Pazopanib tablets can cause severe liver problems, including death. Your healthcare provider will do blood tests to check your liver before you start and while you take pazopanib tablets.

Tell your healthcare provider right away if you get any of these signs of liver problems during treatment with pazopanib tablets:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark urine
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bruise easily
- tiredness
- nausea or vomiting

Your healthcare provider may need to prescribe a lower dose of pazopanib tablets for you or tell you to stop taking pazopanib tablets if you develop liver problems during treatment.

What are pazopanib tablets?

Pazopanib tablets are a prescription medicine used to treat adults with:

- advanced renal cell cancer (RCC)
- advanced soft tissue sarcoma (STS) who have received chemotherapy in the past

It is not known if pazopanib tablets are effective in treating certain soft tissue sarcomas or certain gastrointestinal tumors.

It is not known if pazopanib tablets are safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking pazopanib tablets?

Before taking pazopanib tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have or had liver problems. You may need a lower dose of pazopanib tablets, or your healthcare provider may prescribe a different medicine to treat your advanced renal cell cancer or advanced soft tissue sarcoma.
- have high blood pressure
- have heart problems or an irregular heartbeat, including QT prolongation
- have a history of a stroke
- have headaches, seizures, or vision problems
- have coughed up blood in the last 6 months
- had bleeding of your stomach or intestines in the last 6 months
- have a history of a tear (perforation) in your stomach or intestine, or an abnormal connection between two parts of your gastrointestinal tract (fistula)
- have had blood clots in a vein or in the lung
- have thyroid problems
- had recent surgery or are going to have surgery. You should stop taking pazopanib tablets at least 1 week before scheduled surgery because pazopanib tablets may affect healing after surgery. Do not take pazopanib tablets for at least 2 weeks following major surgery and until your wound heals adequately. Your healthcare provider should tell you when you may start taking pazopanib tablets again after surgery.
- have problems with your kidney function
- are pregnant or plan to become pregnant. Pazopanib tablets can harm your unborn baby. Your healthcare provider should check to see if you are pregnant before you start taking pazopanib tablets. You should not become pregnant while you are taking pazopanib tablets. You should use effective birth control during treatment with pazopanib tablets and for at least 2 weeks after your final dose of pazopanib tablets. Talk to your healthcare provider about types of birth control that may be right for you during this time.
- are a male (including one who has had a vasectomy) with a sexual partner who is pregnant, think that they may be pregnant, or who could become pregnant (including those who use other forms of birth control). You should use condoms during sexual intercourse during treatment with pazopanib tablets and for at least 2 weeks after the last dose of pazopanib tablets.
- are breastfeeding or plan to breastfeed. It is not known if pazopanib tablets pass into your breast milk. Do not breastfeed during treatment with pazopanib tablets and for 2 weeks after the final dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Pazopanib tablets may affect the way other medicines work and other medicines may affect how pazopanib tablets work.

Especially, tell your healthcare provider if you:

- take medicines that can affect how your liver enzymes work, such as:
 - certain antibiotics (used to treat infections)
 - certain medicines used to treat depression
 - certain medicines used to treat HIV-1
 - medicines used to treat irregular heartbeats
- take a medicine that contains simvastatin to treat high cholesterol levels
- take medicines that reduce stomach acid (e.g., esomeprazole)
- drink grapefruit juice

Ask your healthcare provider if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take pazopanib tablets?

- Take pazopanib tablets exactly as your healthcare provider tells you. Your healthcare provider will tell you how much pazopanib tablets to take.
- Your healthcare provider may change your dose.
- Take pazopanib tablets on an empty stomach, at least 1 hour before or 2 hours after food.
- Swallow pazopanib tablets whole. Do not crush pazopanib tablets. It may increase the amount of pazopanib tablets in your body.
- Do not eat grapefruit or drink grapefruit juice during treatment with pazopanib tablets. Grapefruit products may increase the amount of pazopanib in your body.
- If you miss a dose, take it as soon as you remember. Do not take it if it is close (within 12 hours) to your next dose. Just take the next dose at your regular time. Do not take more than 1 dose of pazopanib tablets at a time.
- Your healthcare provider will test your urine, blood, and heart before you start and while you take pazopanib tablets.

What are the possible side effects of pazopanib tablets?

Pazopanib tablets may cause serious side effects, including:

- See “What is the most important information I should know about pazopanib tablets?”
- **irregular or fast heartbeat or fainting**
- **heart failure.** This is a condition where your heart does not pump as well as it should and may cause you to have shortness of breath.
- **bleeding problems.** These bleeding problems may be severe and cause death.

Symptoms may include: unusual bleeding, bruising, or wounds that do not heal.

- **heart attack or stroke.** Heart attack and stroke can happen with pazopanib tablets and may cause death.
Symptoms may include: chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, numbness or weakness on one side of your body, trouble talking, headache, or dizziness.
- **blood clots.** Blood clots may form in a vein, especially in your legs (deep vein thrombosis or DVT). Pieces of a blood clot may travel to your lungs (pulmonary embolism). This may be life-threatening and cause death.
Symptoms may include: new chest pain, trouble breathing or shortness of breath that starts suddenly, leg pain, and swelling of the arms and hands, or legs and feet, a cool or pale arm or leg.
- **Thrombotic microangiopathy (TMA), including thrombotic thrombocytopenia purpura (TTP) and hemolytic uremic syndrome (HUS).** TMA is a condition involving blood clots that can happen while taking pazopanib tablets. TMA is accompanied by a decrease in red blood cells and cells that are involved in clotting. TMA may harm organs, such as the brain and kidneys.
- **tear in your stomach or intestinal wall (perforation) or an abnormal connection between two parts of your gastrointestinal tract (fistula).**
Symptoms may include: pain, swelling in your stomach area, vomiting blood, and black sticky stools.
- **lung problems.** Pazopanib tablets may cause lung problems that may lead to death. Tell your healthcare provider right away if you get a cough that will not go away or shortness of breath.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** PRES is a condition that can happen while taking pazopanib tablets that may cause death.
Symptoms may include: headaches, seizures, lack of energy, confusion, high blood pressure, loss of speech, blindness or changes in vision, and problems thinking.
- **high blood pressure. High blood pressure can happen with pazopanib tablets, including a sudden and severe rise in blood pressure which may be life-threatening.** These blood pressure increases usually happen in the first several months of treatment. Your blood pressure should be well controlled before you start taking pazopanib tablets. Your healthcare provider should begin checking your blood pressure within 1 week of you starting pazopanib tablets and often during treatment to make sure that your blood pressure is well controlled.
Have someone call your healthcare provider or get medical help right away for you, if you get symptoms of a severe increase in blood pressure, including: severe chest pain, severe headache, blurred vision, confusion, nausea and vomiting, severe anxiety, shortness of breath, seizures, or you pass out (become unconscious).
- **thyroid problems.** Your healthcare provider should check you for this during treatment with pazopanib tablets.
- **Tumor lysis syndrome (TLS).** TLS is a condition that can happen during treatment with pazopanib tablets that may cause death. TLS is caused by a fast breakdown of cancer cells. Your healthcare provider may do a blood test to check you for TLS. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with pazopanib tablets: irregular heartbeat, seizures, confusion, muscle cramps or spasms, or a decrease in urine output.
- **protein in your urine.** Your healthcare provider will check you for this problem. If there is too much protein in your urine, your healthcare provider may tell you to stop taking pazopanib tablets.
- **serious infections. Serious infections can happen with pazopanib tablets and can cause death.**
Symptoms of an infection may include: fever, cold symptoms, such as runny nose or sore throat that do not go away, flu symptoms, such as cough, tiredness, and body aches, pain when urinating, cuts, scrapes or wounds that are red, warm, swollen or painful.
- **collapsed lung (pneumothorax).** A collapsed lung can happen with pazopanib tablets. Air may get trapped in the space between your lung and chest wall. This may cause you to have shortness of breath.

Call your healthcare provider right away if you have any of the symptoms listed above.

The most common side effects in people who take pazopanib tablets include:

- diarrhea
- change in hair color
- nausea or vomitin
- loss of appetite

Other common side effects in people with advanced soft tissue sarcoma who take pazopanib tablets include:

- feeling tire
- taste change
- muscle or bone pai
- headach
- tumor pai
- change in skin color
- decreased weigh
- trouble breathin
- stomach pain

These are not all the possible side effects of pazopanib tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Pazopanib tablets?

Store pazopanib tablets at room temperature between 68°F and 77°F (20°C to 25°C).

Keep pazopanib tablets and all medicines out of the reach of children.

General information about the safe and effective use of pazopanib tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use pazopanib tablets for a condition for which it was not prescribed. Do not give pazopanib tablets to other people even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about pazopanib tablets that is written for healthcare professionals.

What are the ingredients in pazopanib tablets?

Active ingredient: pazopanib.

Inactive ingredients: Tablet core: magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.

Coating: hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxide black, polyethylene glycol 8000, and titanium dioxide.

For more information, go to www.apotex.com or call 1-800-706-5575.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

APOTEX INC.

PAZOPANIB TABLETS

200 mg

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Manufactured for:

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