

MEDICATION GUIDE

VOTRIENT[®] (VO-tree-ent) (pazopanib) tablets

Read the Medication Guide that comes with VOTRIENT before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about VOTRIENT?

- **VOTRIENT can cause serious liver problems including death.** Your healthcare provider will do blood tests to check your liver before you start and while you take VOTRIENT.

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

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

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

What is VOTRIENT?

VOTRIENT is a prescription medicine used to treat people with:

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

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

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

What should I tell my healthcare provider before taking VOTRIENT?

Before you take VOTRIENT, tell your healthcare provider if you:

- have or had liver problems. You may need a lower dose of VOTRIENT 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 (within the last 7 days) or are going to have surgery
- have any other medical conditions
- are pregnant or plan to become pregnant. VOTRIENT can harm your unborn baby. You should not become pregnant while you are taking VOTRIENT.
- are breastfeeding or plan to breastfeed. It is not known if VOTRIENT passes into your breast milk. You and your healthcare provider should decide if you will take VOTRIENT or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. VOTRIENT may affect the way other medicines work and other medicines may affect how VOTRIENT works.

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 HIV
 - certain medicines used to treat depression
 - medicines used to treat irregular heart beats
- take a medicine that contains simvastatin to treat high cholesterol levels
- 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 VOTRIENT?

- Take VOTRIENT exactly as your healthcare provider tells you. Your healthcare provider will tell you how much VOTRIENT to take.
- Your healthcare provider may change your dose.
- Take VOTRIENT on an empty stomach, at least 1 hour before or 2 hours after food.
- Do not crush VOTRIENT tablets.
- Do not eat grapefruit or drink grapefruit juice during treatment with VOTRIENT. Grapefruit products may increase the amount of VOTRIENT 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 VOTRIENT at a time.
- Your healthcare provider will test your urine, blood, and heart before you start and while you take VOTRIENT.
- Tell your healthcare provider if you plan to have surgery while taking VOTRIENT. You will need to stop taking VOTRIENT at least 7 days before surgery because VOTRIENT may affect healing after surgery.

What are the possible side effects of VOTRIENT?

VOTRIENT may cause serious side effects including:

- See “**What is the most important information I should know about VOTRIENT?**”
- **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.
- **heart attack or stroke.** Heart attack and stroke can happen with VOTRIENT 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.
- **bleeding problems.** These bleeding problems may be severe and cause death.
Symptoms may include: unusual bleeding, bruising, or wounds that do not heal.

- **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.
- **Reversible Posterior Leukoencephalopathy (RPLS).** RPLS is a condition that can happen while taking VOTRIENT that may cause death. **Symptoms may include:** headaches, seizures, lack of energy, confusion, high blood pressure, blindness or changes in vision, and problems thinking.
- **high blood pressure. High blood pressure can happen with VOTRIENT, 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 VOTRIENT. Your healthcare provider should begin checking your blood pressure within 1 week of you starting VOTRIENT 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 VOTRIENT.
- **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 VOTRIENT.
- **serious infections. Serious infections can happen with VOTRIENT 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 VOTRIENT. 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 VOTRIENT include:

- diarrhea

- change in hair color
- nausea or vomiting
- loss of appetite

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

- feeling tired
- decreased weight
- tumor pain
- muscle or bone pain
- headache
- taste changes
- trouble breathing
- change in skin color

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of VOTRIENT. For more information, ask your healthcare provider or pharmacist.

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 VOTRIENT tablets?

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

Keep VOTRIENT and all medicines out of the reach of children.

General information about the safe and effective use of VOTRIENT.

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

This Medication Guide summarizes the most important information about VOTRIENT. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about VOTRIENT that is written for healthcare professionals. For more information, go to www.VOTRIENT.com or call 1-888-825-5249.

What are the ingredients in VOTRIENT?

Active ingredient: pazopanib.

Inactive ingredients: Tablet core: Magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate. **Coating:** Gray film-coat: Hypromellose, iron oxide black, macrogol/polyethylene glycol 400 (PEG 400), polysorbate 80, titanium dioxide.

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



GlaxoSmithKline
Research Triangle Park, NC 27709

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