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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 advanced renal cell cancer in adults.

It is not known if VOTRIENT is safe or 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.
- have high blood pressure
- have heart problems or an irregular heartbeat including QT prolongation

- 625 • have a history of a stroke
- 626 • have coughed up blood in the last 6 months
- 627 • had bleeding of your stomach or intestines in the last 6 months
- 628 • have a history of a tear (perforation) in your stomach or intestine, or an
- 629 abnormal connection between two parts of your gastrointestinal tract (fistula)
- 630 • have thyroid problems
- 631 • had recent surgery (within the last 7 days) or are going to have surgery
- 632 • have any other medical conditions
- 633 • are pregnant or plan to become pregnant. VOTRIENT can harm your unborn
- 634 baby. You should not become pregnant while you are taking VOTRIENT.
- 635 • are breast-feeding or plan to breast-feed. It is not known if VOTRIENT passes
- 636 into your breast milk. You and your healthcare provider should decide if you will
- 637 take VOTRIENT or breast-feed. You should not do both.

638

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

643

644 **Especially, tell your healthcare provider if you:**

- 645 • take medicines that can affect how your liver enzymes work such as:
 - 646 • certain antibiotics (used to treat infections)
 - 647 • certain medicines used to treat HIV
 - 648 • certain medicines used to treat depression
 - 649 • medicines used to treat irregular heart beats
- 650 • take a medicine that contains simvastatin to treat high cholesterol levels
- 651 • drink grapefruit juice

652

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

655

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

658

659 **How should I take VOTRIENT?**

- 660 • Take VOTRIENT exactly as your healthcare provider tells you. Your healthcare
- 661 provider will tell you how much VOTRIENT to take.
- 662 • Your healthcare provider may change your dose.
- 663 • Take VOTRIENT on an empty stomach, at least 1 hour before or 2 hours after
- 664 food.

- 665 • Do not crush tablets of VOTRIENT.
- 666 • Do not eat grapefruit or drink grapefruit juice during treatment with VOTRIENT.
- 667 Grapefruit products may increase the amount of VOTRIENT in your body.
- 668 • If you miss a dose, take it as soon as you remember. Do not take it if it is close
- 669 (within 12 hours) to your next dose. Just take the next dose at your regular
- 670 time. Do not take more than 1 dose of VOTRIENT at a time.
- 671 • Your healthcare provider will test your blood and heart before you start and
- 672 while you take VOTRIENT.

673

674 **What are the possible side effects of VOTRIENT?**

675 **VOTRIENT may cause serious side effects including:**

- 676 • See **“What is the most important information I should know about**
- 677 **VOTRIENT?”**
- 678 • **irregular or fast heartbeat or fainting**
- 679 • **bleeding problems.** Symptoms may include: unusual bleeding, bruising,
- 680 wounds that do not heal.
- 681 • **heart attack or stroke.** Symptoms may include: chest pain or pressure, pain
- 682 in your arms, back, neck or jaw, shortness of breath, numbness or weakness on
- 683 one side of your body, trouble talking, headache, or dizziness.
- 684 • **tear in your stomach or intestinal wall (perforation) or bleeding.**
- 685 Symptoms may include: pain, swelling in your stomach-area, vomiting blood,
- 686 and black sticky stools.
- 687 • **high blood pressure** including a sudden and severe rise in blood pressure
- 688 which may be life-threatening
- 689 **Have someone call your healthcare provider or get medical help right**
- 690 **away** for you, if you get symptoms of a severe increase in blood pressure,
- 691 including:
- 692 severe chest pain, severe headache, nausea and vomiting, severe anxiety,
- 693 shortness of breath, seizures, or you pass out (become unconscious).
- 694 • **thyroid problems.** Your healthcare provider may check you for this during
- 695 treatment with VOTRIENT.

696

697 **Call your healthcare provider right away, if you have any of the symptoms**

698 **listed above.**

699

700 The most common side effects of VOTRIENT include:

- 701 • diarrhea
- 702 • change in hair color
- 703 • nausea or vomiting
- 704 • loss of appetite

705 • feeling tired

706

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

709

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

712

713 Call your doctor for medical advice about side effects. You may report side effects
714 to FDA at 1-800-FDA-1088.

715

716 **How should I store VOTRIENT tablets?**

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

718

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

720

721 **General information about the safe and effective use of VOTRIENT:**

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

726

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

732

733 **What are the ingredients in VOTRIENT?**

734 **Active Ingredient:** pazopanib.

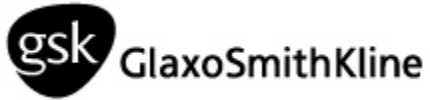
735

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

740

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

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745 GlaxoSmithKline

746 Research Triangle Park, NC 27709

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748 | Revised: March 2012

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