

1 **MEDICATION GUIDE**

2
3 **VOTRIENT® (VO-tree-ent)**
4 **(pazopanib)**
5 **tablets**
6

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

11
12 **What is the most important information I should know about VOTRIENT?**

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

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

- 18 • yellowing of your skin or the whites of your eyes (jaundice)
19 • dark urine
20 • tiredness
21 • nausea or vomiting
22 • loss of appetite
23 • pain on the right side of your stomach area (abdomen)
24 • bruise easily
25

26 Your healthcare provider may need to prescribe a lower dose of VOTRIENT for you
27 or tell you to stop taking VOTRIENT if you develop liver problems during treatment.
28

29 **What is VOTRIENT?**

30 VOTRIENT is a prescription medicine used to treat people with:

- 31 • advanced renal cell cancer (RCC)
32 • advanced soft tissue sarcoma (STS) who have received chemotherapy in the
33 past.

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

36 It is not known if VOTRIENT is safe and effective in children under 18 years of age.
37

38 **What should I tell my healthcare provider before taking VOTRIENT?**

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

- 40 • have or had liver problems. You may need a lower dose of VOTRIENT or your

41 healthcare provider may prescribe a different medicine to treat your advanced
42 renal cell cancer or advanced soft tissue sarcoma.

- 43 • have high blood pressure
- 44 • have heart problems or an irregular heartbeat including QT prolongation
- 45 • have a history of a stroke
- 46 • have headaches, seizures, or vision problems
- 47 • have coughed up blood in the last 6 months
- 48 • had bleeding of your stomach or intestines in the last 6 months
- 49 • have a history of a tear (perforation) in your stomach or intestine, or an
- 50 abnormal connection between two parts of your gastrointestinal tract (fistula)
- 51 • have had blood clots in a vein or in the lung
- 52 • have thyroid problems
- 53 • had recent surgery (within the last 7 days) or are going to have surgery
- 54 • have any other medical conditions
- 55 • are pregnant or plan to become pregnant. VOTRIENT can harm your unborn
- 56 baby. You should not become pregnant while you are taking VOTRIENT.
- 57 • are breastfeeding or plan to breastfeed. It is not known if VOTRIENT passes
- 58 into your breast milk. You and your healthcare provider should decide if you will
- 59 take VOTRIENT or breastfeed. You should not do both.

60

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

65

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

- 67 • take medicines that can affect how your liver enzymes work such as:
 - 68 • certain antibiotics (used to treat infections)
 - 69 • certain medicines used to treat HIV
 - 70 • certain medicines used to treat depression
 - 71 • medicines used to treat irregular heart beats
- 72 • take a medicine that contains simvastatin to treat high cholesterol levels
- 73 • drink grapefruit juice

74

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

77

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

80

81 **How should I take VOTRIENT?**

- 82 • Take VOTRIENT exactly as your healthcare provider tells you. Your healthcare
83 provider will tell you how much VOTRIENT to take.
- 84 • Your healthcare provider may change your dose.
- 85 • Take VOTRIENT on an empty stomach, at least 1 hour before or 2 hours after
86 food.
- 87 • Do not crush VOTRIENT tablets.
- 88 • Do not eat grapefruit or drink grapefruit juice during treatment with VOTRIENT.
89 Grapefruit products may increase the amount of VOTRIENT in your body.
- 90 • If you miss a dose, take it as soon as you remember. Do not take it if it is close
91 (within 12 hours) to your next dose. Just take the next dose at your regular
92 time. Do not take more than 1 dose of VOTRIENT at a time.
- 93 • Your healthcare provider will test your urine, blood, and heart before you start
94 and while you take VOTRIENT.
- 95 • Tell your healthcare provider if you plan to have surgery while taking
96 VOTRIENT. You will need to stop taking VOTRIENT at least 7 days before
97 surgery because VOTRIENT may affect healing after surgery.

98

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

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

- 101 • See **“What is the most important information I should know about**
102 **VOTRIENT?”**
- 103 • **irregular or fast heartbeat or fainting**
- 104 • **heart failure.** This is a condition where your heart does not pump as well as it
105 should and may cause you to have shortness of breath.
- 106 • **heart attack or stroke.** Heart attack and stroke can happen with VOTRIENT
107 and may cause death.
108 **Symptoms may include:** chest pain or pressure, pain in your arms, back,
109 neck or jaw, shortness of breath, numbness or weakness on one side of your
110 body, trouble talking, headache, or dizziness.
- 111 • **blood clots.** Blood clots may form in a vein, especially in your legs (deep vein
112 thrombosis or DVT). Pieces of a blood clot may travel to your lungs (pulmonary
113 embolism). This may be life threatening and cause death.
114 **Symptoms may include:** new chest pain, trouble breathing or shortness of
115 breath that starts suddenly, leg pain, and swelling of the arms and hands, or
116 legs and feet, a cool or pale arm or leg.
- 117 • **bleeding problems.** These bleeding problems may be severe and cause death.
118 **Symptoms may include:** unusual bleeding, bruising, wounds that do not heal.
- 119 • **tear in your stomach or intestinal wall (perforation) or an abnormal**
120 **connection between two parts of your gastrointestinal tract (fistula).**

121 **Symptoms may include:** pain, swelling in your stomach-area, vomiting blood,
122 and black sticky stools.

123 • **Reversible Posterior Leukoencephalopathy (RPLS).** RPLS is a condition
124 that can happen while taking VOTRIENT that may cause death.

125 **Symptoms may include:** headaches, seizures, lack of energy, confusion, high
126 blood pressure, blindness or changes in vision, and problems thinking.

127 • **high blood pressure. High blood pressure can happen with VOTRIENT,**
128 **including a sudden and severe rise in blood pressure which may be life-**
129 **threatening.** These blood pressure increases usually happen in the first

130 several months of treatment. Your blood pressure should be well controlled

131 before you start taking VOTRIENT. Your healthcare provider should begin
132 checking your blood pressure within 1 week of you starting VOTRIENT and

133 often during treatment to make sure that your blood pressure is well controlled.

134 **Have someone call your healthcare provider or get medical help right**

135 **away** for you, if you get symptoms of a severe increase in blood pressure,

136 including: severe chest pain, severe headache, blurred vision, confusion,

137 nausea and vomiting, severe anxiety, shortness of breath, seizures, or you pass

138 out (become unconscious).

139 • **thyroid problems.** Your healthcare provider should check you for this during
140 treatment with VOTRIENT.

141 • **protein in your urine.** Your healthcare provider will check you for this
142 problem. If there is too much protein in your urine, your healthcare provider
143 may tell you to stop taking VOTRIENT.

144 • **serious infections. Serious infections can happen with VOTRIENT and**
145 **can cause death.**

146 **Symptoms of an infection may include:** fever, cold symptoms, such as

147 runny nose or sore throat that do not go away, flu symptoms, such as cough,

148 tiredness, and body aches, pain when urinating, cuts, scrapes or wounds that

149 are red, warm, swollen or painful.

150 • **collapsed lung (pneumothorax).** A collapsed lung can happen with

151 VOTRIENT. Air may get trapped in the space between your lung and chest wall.

152 This may cause you to have shortness of breath.

153

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

156

157 The most common side effects in people who take VOTRIENT include:

158 • diarrhea

159 • change in hair color

160 • nausea or vomiting

- 161 • loss of appetite
- 162 Other common side effects in people with advanced soft tissue sarcoma who take
163 VOTRIENT include:
- 164 • feeling tired
 - 165 • decreased weight
 - 166 • tumor pain
 - 167 • muscle or bone pain
 - 168 • headache
 - 169 • taste changes
 - 170 • trouble breathing
 - 171 • change in skin color

172

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

175

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

178

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

181

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

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

184

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

186

187 **General information about the safe and effective use of VOTRIENT.**

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

192

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

198

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

200 **Active ingredient:** pazopanib.

201

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

206

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

209



210

211 GlaxoSmithKline

212 Research Triangle Park, NC 27709

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220 VTR: XMG