

1 **MEDICATION GUIDE**

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3 **PROMACTA® (pro-MAC-ta)**  
4 **(eltrombopag)**  
5 **Tablets**  
6

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

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

13 PROMACTA can cause serious side effects, including:

- 14 • **Liver problems.** PROMACTA may damage your liver and cause serious illness  
15 and death. You must have blood tests to check your liver before you start taking  
16 PROMACTA and during treatment with PROMACTA. Your healthcare provider will  
17 order these blood tests. In some cases PROMACTA treatment may need to be  
18 stopped. Tell your healthcare provider right away if you have any of these signs  
19 and symptoms of liver problems:
  - 20 • yellowing of the skin or the whites of the eyes (jaundice)
  - 21 • unusual darkening of the urine
  - 22 • unusual tiredness
  - 23 • right upper stomach area pain
- 24 • **Bone marrow changes (increased reticulin and possible bone marrow**  
25 **fibrosis).** Long-term use of PROMACTA may cause changes in your bone  
26 marrow. These changes may lead to abnormal blood cells or your body making  
27 less blood cells. The mild form of these bone marrow changes is called  
28 “increased reticulin” which may progress to a more severe form called “fibrosis”.  
29 The mild form may cause no problems while the severe form may cause life-  
30 threatening blood problems. Signs of bone marrow changes may show up as  
31 abnormal results in your blood tests. Your healthcare provider will decide if  
32 abnormal blood test results mean that you should have bone marrow tests or if  
33 you should stop taking PROMACTA.
- 34 • **High platelet counts and higher chance for blood clots.** Your chance of  
35 getting a blood clot is increased if your platelet count is too high during  
36 treatment with PROMACTA. Your chance of getting a blood clot may also be  
37 increased during treatment with PROMACTA if you have normal or low platelet  
38 counts. You may have severe problems or die from some forms of blood clots,  
39 such as clots that travel to the lungs or that cause heart attacks or strokes. Your  
40 healthcare provider will check your blood platelet counts, and change your dose

41 or stop PROMACTA if your platelet counts get too high. Tell your healthcare  
42 provider right away if you have signs and symptoms of a blood clot in the leg,  
43 such as swelling, pain, or tenderness in your leg.

44 People with chronic liver disease may be at risk for a type of blood clot in the  
45 stomach area. Stomach area pain may be a symptom of this type of blood clot.

- 46 • **Worsening of blood cancers.** PROMACTA is not for use in people with blood  
47 cancer or a precancerous condition called myelodysplastic syndrome (MDS). If  
48 you have one of these conditions, PROMACTA may worsen your cancer or  
49 condition and may cause you to die sooner.
- 50 • **New or worsened cataracts (a clouding of the lens in the eye).** New  
51 or worsened cataracts have happened in people taking PROMACTA. Your  
52 healthcare provider will check your eyes before and during your treatment with  
53 PROMACTA. Tell your healthcare provider about any changes in your eyesight  
54 while taking PROMACTA.

55

56 When you are being treated with PROMACTA, your healthcare provider will closely  
57 monitor your dose of PROMACTA and blood tests, including platelet counts and liver  
58 tests.

59

60 **See “What are the possible side effects of PROMACTA?” for other side**  
61 **effects of PROMACTA.**

62

### 63 **What is PROMACTA?**

64 PROMACTA is a prescription medicine used to treat low blood platelet counts in  
65 adults with chronic immune (idiopathic) thrombocytopenia (ITP), when other  
66 medicines to treat your ITP or surgery to remove the spleen have not worked well  
67 enough.

68

69 PROMACTA is used to try to keep your platelet count about 50,000 per microliter in  
70 order to lower your risk for bleeding. PROMACTA is not used to make your platelet  
71 count normal.

72

73 It is not known if PROMACTA works or if it is safe in people under the age of 18  
74 years.

75

76 PROMACTA is for treatment of certain people with low platelet counts caused by  
77 chronic ITP, not low platelet counts caused by other conditions or diseases.

78

### 79 **What should I tell my healthcare provider before taking PROMACTA?**

80 **Before you take PROMACTA, tell your healthcare provider if you:**

- 81 • have liver or kidney problems
- 82 • have or had a blood clot
- 83 • have a history of cataracts
- 84 • have had surgery to remove your spleen (splenectomy)
- 85 • have a bone marrow problem, including a blood cancer or Myelodysplastic
- 86     Syndrome (MDS)
- 87 • have bleeding problems
- 88 • are Asian and you are of Chinese, Japanese, Taiwanese, or Korean ancestry, you
- 89     may need a lower dose of PROMACTA.
- 90 • have any other medical conditions
- 91 • are pregnant, think you may be pregnant, or plan to get pregnant. It is not
- 92     known if PROMACTA will harm an unborn baby.
- 93     ***Pregnancy Registry:*** There is a registry for women who become pregnant
- 94     during treatment with PROMACTA. If you become pregnant, consider this
- 95     registry. The purpose of the registry is to collect safety information about the
- 96     health of you and your baby. Contact the registry as soon as you become aware
- 97     of the pregnancy, or ask your healthcare provider to contact the registry for
- 98     you. You and your healthcare provider can get information and enroll in the
- 99     registry by calling 1-888-825-5249.
- 100 • are breast-feeding or plan to breast-feed. It is not known if PROMACTA passes
- 101     into your breast milk. You and your healthcare provider should decide whether
- 102     you will take PROMACTA or breast-feed. You should not do both.

103

104 **Tell your healthcare provider about all the medicines you take**, including

105 prescription and non-prescription medicines, vitamins, and herbal products.

106 PROMACTA may affect the way certain medicines work. Certain other medicines

107 may affect the way PROMACTA works.

108

109 Especially tell your healthcare provider if you take:

- 110 • certain medicines used to treat high cholesterol, called “statins”.
- 111 • a blood thinner medicine.

112

113 Certain medicines may keep PROMACTA from working correctly. Take PROMACTA

114 either 4 hours before or 4 hours after taking these products:

- 115 • antacids used to treat stomach ulcers or heartburn.
- 116 • multivitamins or products that contain iron, calcium, aluminum, magnesium,
- 117     selenium, and zinc which may be found in mineral supplements.

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

119 above.

120

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

123

#### 124 **How should I take PROMACTA?**

- 125 • Take PROMACTA exactly as your healthcare provider tells you. Do not stop using  
126 PROMACTA without talking with your healthcare provider first. Do not change  
127 your dose or schedule for taking PROMACTA unless your healthcare provider  
128 tells you to change it.
- 129 • Take PROMACTA on an empty stomach, either 1 hour before or 2 hours after  
130 eating food.
- 131 • Take PROMACTA at least 4 hours before or 4 hours after eating dairy products  
132 and calcium fortified juices.
- 133 • If you miss a dose of PROMACTA, wait and take your next scheduled dose. Do  
134 not take more than one dose of PROMACTA in one day.
- 135 • If you take too much PROMACTA, you may have a higher chance of serious side  
136 effects. Call your healthcare provider right away.
- 137 • Your healthcare provider will check your platelet count every week and change  
138 your dose of PROMACTA as needed. This will happen every week until your  
139 healthcare provider decides that your dose of PROMACTA can stay the same.  
140 After that, you will need to have blood tests every month. When you stop taking  
141 PROMACTA, you will need to have blood tests for at least 4 weeks to check if  
142 your platelet count drops too low.
- 143 • Tell your healthcare provider about any bruising or bleeding that happens while  
144 you take and after you stop taking PROMACTA.

145

#### 146 **What should I avoid while taking PROMACTA?**

147 Avoid situations and medicines that may increase your risk of bleeding.

148

#### 149 **What are the possible side effects of PROMACTA?**

150 PROMACTA may cause serious side effects.

151

152 See **“What is the most important information I should know about  
153 PROMACTA?”**.

154

155 The most common side effects of PROMACTA are:

- 156 • nausea
- 157 • diarrhea
- 158 • upper respiratory tract infection; symptoms may include runny nose, stuffy  
159 nose, and sneezing
- 160 • vomiting

- 161 • muscle aches
- 162 • urinary tract infections; symptoms may include frequent or urgent need to
- 163 urinate, low fever in some people, pain or burning with urination
- 164 • pain or swelling (inflammation) in your throat or mouth (oropharyngeal pain and
- 165 pharyngitis)
- 166 • abnormal liver function tests
- 167 • abnormal skin sensations such as tingling, itching, or burning
- 168 • back pain
- 169 • 'flu' symptoms (influenza); symptoms may include fever, headache, tiredness,
- 170 cough, sore throat, and body aches
- 171 • rash
- 172

173 These are not all the possible side effects of PROMACTA. Tell your healthcare  
174 provider if you have any side effect that bothers you or that does not go away. For  
175 more information, ask your healthcare provider or pharmacist.

176  
177 Call your doctor for medical advice about side effects. You may report side effects  
178 to FDA at 1-800-FDA-1088.

179  
180 **How should I store PROMACTA Tablets?**

- 181 • Store at room temperature between 59°F to 86°F (15°C to 30°C).
- 182 • **Keep PROMACTA and all medicines out of the reach of children.**
- 183

184 **General information about the safe and effective use of PROMACTA**

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

189  
190 This Medication Guide summarizes the most important information about  
191 PROMACTA. If you would like more information, talk with your healthcare provider.  
192 You can ask your healthcare provider or pharmacist for information about  
193 PROMACTA that is written for healthcare professionals.

194  
195 For more information, go to [www.PROMACTA.com](http://www.PROMACTA.com) or call toll-free 1-888-825-5249.

196  
197 **What are the ingredients in PROMACTA?**

198 Active ingredient: eltrombopag olamine.

199 Inactive ingredients:

- 200 • Tablet Core: Magnesium stearate, mannitol, microcrystalline cellulose, povidone,  
201 and sodium starch glycolate.
- 202 • Coating: Hypromellose, polyethylene glycol 400, titanium dioxide, polysorbate  
203 80 (12.5 mg tablet), and FD&C Yellow No. 6 aluminum lake (25 mg tablet),  
204 FD&C Blue No. 2 aluminum lake (50 mg tablet), or Iron Oxide Red and Iron  
205 Oxide Black (75 mg tablet).

206

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

209

210 PROMACTA is a registered trademark of GlaxoSmithKline.

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213 GlaxoSmithKline

214 Research Triangle Park, NC 27709

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