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MEDICATION GUIDE

PROMACTA[®] (pro-MAC-ta) (eltrombopag) Tablets

Read the Medication Guide that comes with PROMACTA 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 PROMACTA?

PROMACTA can cause uncommon but serious side effects:

- **Liver problems.** PROMACTA may damage your liver and cause serious illness and death. You must have blood tests to check your liver before you start taking PROMACTA and during treatment with PROMACTA. Your healthcare provider will order these blood tests. In some cases PROMACTA treatment may need to be stopped. Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems:
 - yellowing of the skin or the whites of the eyes (jaundice),
 - unusual darkening of the urine,
 - unusual tiredness,
 - right upper stomach area pain.
- **Bone marrow changes (increased reticulin and possible bone marrow fibrosis).** Long-term use of PROMACTA may cause changes in your bone marrow. These changes may lead to abnormal blood cells or your body making less blood cells. The mild form of these bone marrow changes is called “increased reticulin”. It is not known if this may progress to a more severe form called “fibrosis.” The mild form may cause no problems while the severe form may cause life-threatening blood problems. Signs of bone marrow changes may show up as abnormal results in your blood tests. Your healthcare provider will decide if abnormal blood test results mean that you should have bone marrow tests or if you should stop taking PROMACTA.
- **Worsening low blood platelet count (thrombocytopenia) and risk of bleeding shortly after stopping PROMACTA.** When you stop taking PROMACTA, your low blood platelet count (thrombocytopenia) may become worse than before you started taking PROMACTA. These effects are most likely to happen within 4 weeks after you stop taking PROMACTA. The lower platelet counts during this time period may increase your risk of bleeding, especially if you take a blood thinner or other medicines that affects platelets. Your healthcare provider will check your blood platelet counts for at least 4 weeks after you stop taking PROMACTA. Call your healthcare provider right away to report any bruising or bleeding.

- 40 • **High platelet counts and higher chance for blood clots.** You have a higher chance of
41 getting a blood clot if your platelet count is too high during treatment with PROMACTA.
42 You may have severe complications or die from some forms of blood clots, such as clots that
43 travel to the lungs or that cause heart attacks or strokes. Your healthcare provider will check
44 your blood platelet counts, and change your dose or stop PROMACTA if your platelet counts
45 get too high.
- 46 • **Worsening of blood cancers.** PROMACTA is not for use in patients with blood cancer or a
47 precancerous condition called myelodysplastic syndrome (MDS). If you have one of these
48 conditions, PROMACTA may worsen your cancer or condition and may cause you to die
49 sooner.

50
51 When you are being treated with PROMACTA, your healthcare provider will closely monitor
52 your dose of PROMACTA and blood tests, including platelet counts and liver tests.

53
54 PROMACTA is available only through a program called “PROMACTA CARES”. To receive
55 PROMACTA, you must talk to your healthcare provider, understand the benefits and risks of
56 PROMACTA and agree to enroll into PROMACTA CARES.

- 57 • During therapy with PROMACTA, your healthcare provider may change your dose of
58 PROMACTA, depending upon the change in your blood platelet count. You must have blood
59 platelet count tests done before, during and after your therapy with PROMACTA.
- 60 • PROMACTA is used to try to keep your platelet count about 50,000 per microliter in order to
61 lower your risk for bleeding. PROMACTA is not used to make your platelet count normal.

62
63 **See “What are the possible side effects of PROMACTA?” for other side effects of**
64 **PROMACTA.**

65 66 **What is PROMACTA?**

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

70 71 **PROMACTA is only:**

- 72 • prescribed by healthcare providers who are enrolled in PROMACTA CARES.
- 73 • given to people who are enrolled in PROMACTA CARES.

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

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

79

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

81 **Tell your healthcare provider if you:**

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

101

102 **Tell your healthcare provider about all the medicines you take**, including prescription and
103 non-prescription medicines, vitamins, and herbal products. PROMACTA may affect the way
104 certain medicines work. Certain other medicines may affect the way PROMACTA works.

105

106 Especially tell your healthcare provider if you take:

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

109

110 Certain medicines may keep PROMACTA from working correctly. Take PROMACTA either
111 4 hours before or 4 hours after taking these products:

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

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

116

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

119

120 **How should I take PROMACTA?**

121 To receive PROMACTA, you must first talk with your healthcare provider and understand the
122 benefits and risks of PROMACTA. You must agree to and follow all of the instructions in
123 PROMACTA CARES.

- 124
- 125 • Before you can begin to receive PROMACTA, your healthcare provider will:
 - 126 • explain PROMACTA CARES to you.
 - 127 • answer all of your questions about PROMACTA and PROMACTA CARES.
 - 128 • make sure you read this PROMACTA Medication Guide.
 - 129 • have you sign the PROMACTA CARES Patient Enrollment Form.
 - 130 • Take PROMACTA exactly as your healthcare provider tells you. Do not stop using
131 PROMACTA without talking with your healthcare provider first. Do not change your dose or
132 schedule for taking PROMACTA unless your healthcare provider tells you to change it.
 - 133 • Take PROMACTA on an empty stomach, either 1 hour before or 2 hours after eating food.
 - 134 • Take PROMACTA at least 4 hours before or 4 hours after eating dairy products and calcium
135 fortified juices.
 - 136 • If you miss a dose of PROMACTA, wait and take your next scheduled dose. Do not take
137 more than one dose of PROMACTA in one day.
 - 138 • If you take too much PROMACTA, you may have a higher chance of serious side effects.
139 Call your healthcare provider right away.
 - 140 • Your healthcare provider will check your platelet count every week and change your dose of
141 PROMACTA as needed. This will happen every week until your healthcare provider decides
142 that your dose of PROMACTA can stay the same. After that, you will need to have blood
143 tests every month. When you stop taking PROMACTA, you will need to have blood tests for
144 at least 4 weeks to check if your platelet count drops too low.
 - 145 • Tell your healthcare provider about any bruising or bleeding that happens while you take and
146 after you stop taking PROMACTA.

147

148 **What should I avoid while taking PROMACTA?**

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

150

151 **What are the possible side effects of PROMACTA?**

152 Promacta may cause serious side effects.

153

- 154 • See **“What is the most important information I should know about PROMACTA?”**.
- 155 • **New or worsened cataracts (a clouding of the lens in the eye)**. New or worsened cataracts
156 have happened in people taking PROMACTA. Your healthcare provider will check your
157 eyes before and during your treatment with PROMACTA. Tell your healthcare provider
158 about any changes in your eyesight while taking PROMACTA.

159

- 160 The most common side effects of PROMACTA are:
- 161 • nausea
 - 162 • vomiting
 - 163 • heavy or longer than normal menstrual periods
 - 164 • muscle aches
 - 165 • abnormal skin sensations such as tingling, itching, or burning
 - 166 • indigestion
 - 167 • bruising
 - 168 • bleeding into the tissue that covers the eye and under side of the eyelid (conjunctiva).

169
170 These are not all the possible side effects of PROMACTA. Tell your healthcare provider if you
171 have any side effect that bothers you or that does not go away. For more information, ask your
172 healthcare provider or pharmacist.

173
174 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-
175 800-FDA-1088.

176 177 **How should I store PROMACTA Tablets?**

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

180 181 **What are the ingredients in PROMACTA?**

182 Active Ingredient: eltrombopag olamine.

183 Inactive Ingredients:

- 184 • Tablet Core: Magnesium stearate, mannitol, microcrystalline cellulose, povidone, and
185 sodium starch glycolate.
- 186 • Coating: Hypromellose, polyethylene glycol 400, titanium dioxide, and FD&C Yellow No. 6
187 aluminum lake (25 mg tablet), FD&C Blue No. 2 aluminum lake (50 mg tablet), or Iron
188 Oxide Red and Iron Oxide Black (75 mg tablet).

189 190 **General information about the safe and effective use of PROMACTA**

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

195
196 This Medication Guide summarizes the most important information about PROMACTA. If you
197 would like more information, talk with your healthcare provider. You can ask your healthcare
198 provider or pharmacist for information about PROMACTA that is written for healthcare
199 professionals. For more information you can call toll-free 1-888-825-5249.

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201 PROMACTA is a registered trademark of GlaxoSmithKline.

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

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