

702 **MEDICATION GUIDE**

703
704 **PROMACTA® (pro-MAC-ta)**
705 **(eltrombopag)**
706 **tablets**
707

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

712
713 **What is the most important information I should know about PROMACTA?**
714

715 PROMACTA can cause serious side effects, including:

716
717 **Liver problems.** If you have chronic hepatitis C virus, and take PROMACTA with
718 interferon and ribavirin treatment, PROMACTA may increase your risk of liver
719 problems. Tell your healthcare provider right away if you have any of these signs
720 and symptoms of liver problems:

- 721 • yellowing of the skin or the whites of the eyes (jaundice)
- 722 • unusual darkening of the urine
- 723 • unusual tiredness
- 724 • right upper stomach area pain
- 725 • confusion
- 726 • swelling of the stomach area (abdomen)

727
728 **See “What are the possible side effects of PROMACTA?” for other side**
729 **effects of PROMACTA.**

730
731 **What is PROMACTA?**
732

733 PROMACTA is a prescription medicine used to treat low blood platelet counts in
734 people with:

- 735 • chronic immune (idiopathic) thrombocytopenia (ITP), when other medicines to
736 treat your ITP or surgery to remove the spleen have not worked well enough
- 737 • chronic hepatitis C virus (HCV) infection before and during treatment with
738 interferon

739
740 PROMACTA is used to try to raise your platelet count in order to lower your risk for
741 bleeding.

742

743 PROMACTA is not used to make your platelet count normal.

744

745 PROMACTA is for treatment of certain people with low platelet counts caused by
746 chronic ITP or chronic HCV, not low platelet counts caused by other conditions or
747 diseases.

748

749 It is not known if PROMACTA is safe and effective when used with other antiviral
750 medicines that are approved to treat chronic hepatitis C.

751

752 It is not known if PROMACTA is safe and effective in children.

753

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

755

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

- 757 • have liver or kidney problems
- 758 • have or had a blood clot
- 759 • have a history of cataracts
- 760 • have had surgery to remove your spleen (splenectomy)
- 761 • have bleeding problems
- 762 • are Asian and you are of Chinese, Japanese, Taiwanese, or Korean ancestry. You
763 may need a lower dose of PROMACTA.
- 764 • have any other medical conditions
- 765 • are pregnant or plan to become pregnant. It is not known if PROMACTA will
766 harm an unborn baby.

767 ***Pregnancy Registry:*** There is a registry for women who become pregnant
768 during treatment with PROMACTA. If you become pregnant, consider this
769 registry. The purpose of the registry is to collect safety information about the
770 health of you and your baby. Contact the registry as soon as you become aware
771 of the pregnancy, or ask your healthcare provider to contact the registry for
772 you. You and your healthcare provider can get information and enroll in the
773 registry by calling 1-888-825-5249.

- 774 • are breastfeeding or plan to breastfeed. It is not known if PROMACTA passes
775 into your breast milk. You and your healthcare provider should decide whether
776 you will take PROMACTA or breastfeed. You should not do both.

777

778 **Tell your healthcare provider about all the medicines you take**, including
779 prescription and over-the-counter medicines, vitamins, and herbal supplements.

780 PROMACTA may affect the way certain medicines work. Certain other medicines
781 may affect the way PROMACTA works.

782

783 Especially tell your healthcare provider if you take:

- 784 • certain medicines used to treat high cholesterol, called “statins”
- 785 • a blood thinner medicine

786

787 Certain medicines may keep PROMACTA from working correctly. Take PROMACTA at
788 least 4 hours before or 4 hours after taking these products:

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

792

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

795

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

798

799 **How should I take PROMACTA?**

800

- 801 • Take PROMACTA exactly as your healthcare provider tells you to take it. Do not
802 stop taking PROMACTA without talking with your healthcare provider first. Do
803 not change your dose or schedule for taking PROMACTA unless your healthcare
804 provider tells you to change it.
- 805 • Take PROMACTA on an empty stomach, either 1 hour before or 2 hours after
806 eating food.
- 807 • Take PROMACTA at least 4 hours before or 4 hours after eating dairy products
808 and calcium fortified juices.
- 809 • If you miss a dose of PROMACTA, wait and take your next scheduled dose. Do
810 not take more than one dose of PROMACTA in one day.
- 811 • If you take too much PROMACTA, you may have a higher risk of serious side
812 effects. Call your healthcare provider right away.
- 813 • Your healthcare provider will check your platelet count during your treatment
814 with PROMACTA and change your dose of PROMACTA as needed.
- 815 • Tell your healthcare provider about any bruising or bleeding that happens while
816 you take and after you stop taking PROMACTA.

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

819

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

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

823

824 PROMACTA may cause serious side effects, including:

825

826 • See **“What is the most important information I should know about**
827 **PROMACTA?”**

828 • **Abnormal liver function tests.** Your healthcare provider will order blood tests
829 to check your liver before you start taking PROMACTA and during your
830 treatment. In some cases treatment with PROMACTA may need to be stopped
831 due to changes in your liver function tests.

832 • **High platelet counts and higher risk for blood clots.** Your risk of getting a
833 blood clot is increased if your platelet count is too high during treatment with
834 PROMACTA. Your risk of getting a blood clot may also be increased during
835 treatment with PROMACTA if you have normal or low platelet counts. You may
836 have severe problems or die from some forms of blood clots, such as clots that
837 travel to the lungs or that cause heart attacks or strokes. Your healthcare
838 provider will check your blood platelet counts, and change your dose or stop
839 PROMACTA if your platelet counts get too high. Tell your healthcare provider
840 right away if you have signs and symptoms of a blood clot in the leg, such as
841 swelling, pain, or tenderness in your leg.
842 People with chronic liver disease may be at risk for a type of blood clot in the
843 stomach area. Tell your healthcare provider right away if you have stomach area
844 pain that may be a symptom of this type of blood clot.

845 • **New or worsened cataracts (a clouding of the lens in the eye).** New or
846 worsened cataracts have happened in people taking PROMACTA. Your healthcare
847 provider will check your eyes before and during your treatment with PROMACTA.
848 Tell your healthcare provider about any changes in your eyesight while taking
849 PROMACTA.

850

851 **The most common side effects of PROMACTA when used to treat chronic**
852 **ITP are:**

853 • nausea

854 • diarrhea

855 • upper respiratory tract infection. Symptoms may include runny nose, stuffy
856 nose, and sneezing

857 • vomiting

858 • muscle aches

859 • urinary tract infection. Symptoms may include frequent or urgent need to
860 urinate, low fever in some people, pain or burning with urination.

861 • pain or swelling (inflammation) in your throat or mouth (oropharyngeal pain and

- 862 pharyngitis)
- 863 • abnormal liver function tests
- 864 • back pain
- 865 • "flu" like symptoms (influenza) including fever, headache, tiredness, cough, sore
- 866 throat, and body aches
- 867 • skin tingling, itching, or burning
- 868 • rash

869

870 **The most common side effects when PROMACTA is used in combination**
871 **with other medicines to treat chronic HCV are:**

- 872 • low red blood cell count (anemia)
- 873 • fever
- 874 • tiredness
- 875 • headache
- 876 • nausea
- 877 • diarrhea
- 878 • decreased appetite
- 879 • "flu" like symptoms (influenza) including fever, headache, tiredness, cough, sore
- 880 throat, and body aches
- 881 • feeling weak
- 882 • trouble sleeping
- 883 • cough
- 884 • itching
- 885 • chills
- 886 • muscle aches
- 887 • hair loss
- 888 • swelling in your ankles, feet, and legs

889

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

892

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

895

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

898

899 **How should I store PROMACTA tablets?**

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- 901 • Store PROMACTA at room temperature between 68°F to 77°F (20°C to 25°C).

- 902 • Keep PROMACTA tightly closed in the bottle given to you.
903 • The PROMACTA bottle may contain a desiccant pack to help keep your medicine
904 dry. Do not remove the desiccant pack from the bottle.

905 **Keep PROMACTA and all medicines out of the reach of children.**

906

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

908

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

913

914 This Medication Guide summarizes the most important information about
915 PROMACTA. If you would like more information, talk with your healthcare provider.
916 You can ask your healthcare provider or pharmacist for information about
917 PROMACTA that is written for health professionals.

918

919 For more information about PROMACTA, go to www.PROMACTA.com or call 1-888-
920 825-5249.

921

922 **What are the ingredients in PROMACTA?**

923

924 **Active ingredient:** eltrombopag olamine.

925 **Inactive ingredients:**

- 926 • **Tablet Core:** magnesium stearate, mannitol, microcrystalline cellulose,
927 povidone, and sodium starch glycolate.
- 928 • **Coating:** hypromellose (12.5 mg, 25 mg, 50 mg, and 75 mg tablets) or
929 polyvinyl alcohol and talc (100 mg tablet), polyethylene glycol 400, titanium
930 dioxide, polysorbate 80 (12.5 mg tablet), and FD&C Yellow No. 6 aluminum lake
931 (25 mg tablet), FD&C Blue No. 2 aluminum lake (50 mg tablet), Iron Oxide Red
932 and Iron Oxide Black (75 mg tablet), or Iron Oxide Yellow and Iron Oxide Black
933 (100 mg tablet).

934

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

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938 PROMACTA is a registered trademark of the GlaxoSmithKline group of companies.

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