Approved Uses for PROMACTA®
(eltrombopag) Tablets

PROMACTA is a prescription medicine used to treat people with severe aplastic anemia (SAA) in combination with standard immunosuppressive therapy as the first treatment for adults and children 2 years of age and older. PROMACTA is also used to treat your SAA when other medicines have not worked well enough.

PROMACTA is not used to make platelet counts normal. PROMACTA is for treatment of certain people with low platelet counts caused by chronic immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV), or SAA, not for a precancerous condition called myelodysplastic syndromes (MDS) or low platelet counts caused by other conditions or diseases.

It is not known if PROMACTA is safe and effective in children with chronic HCV or previously treated SAA, in children younger than 1 year with ITP, or children younger than 2 years when used in combination with standard immunosuppressive therapy as the first treatment for SAA.

Important Safety Information for
PROMACTA® (eltrombopag) Tablets

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

PROMACTA can cause serious side effects, including:

Liver problems.
PROMACTA may increase your risk of liver problems that may be severe and possibly life-threatening.

(continued on next page)
WHAT IS SEVERE APLASTIC ANEMIA?

Aplastic anemia is a rare condition that stops the body from making enough blood cells.

Three types of blood cells are affected by this disease:

- Red blood cells
- White blood cells
- Platelets

How is severe aplastic anemia (SAA) diagnosed?

Your doctor will test your blood and bone marrow to find out if you have aplastic anemia. If the results are below a specific level and your bone marrow shows fatty cells, you are diagnosed with severe aplastic anemia.

What are some common symptoms of SAA?

- Bruising easily
- Bleeding that is hard to stop
- Fatigue
- Shortness of breath
- Dizziness
- Flu-like illness

SAA is a rare condition, and it’s important to know that your doctor can treat it.
WHAT ARE YOUR SAA TREATMENT OPTIONS?

Your doctor has a number of options to choose from to treat your SAA. Finding the right therapy and starting early are important to treating SAA. Let’s talk about some of the most commonly used options.

Blood Transfusion
While this is a short-term treatment, it can keep your blood cells at higher levels to help with some of the symptoms you may be experiencing. Blood transfusion is often used in addition to the other options shown here.

Bone Marrow Stem Cell Transplant
This procedure replaces damaged stem cells in your bone marrow with healthy ones from a matched donor. This helps your body start making blood cells on its own again. For patients who have a matched donor, this is the preferred treatment regimen.

Immunosuppressive Therapies
These medications prevent your immune system from attacking your bone marrow, allowing the body to make new blood cells. For SAA, the most commonly used are antithymocyte globulin (ATG) and cyclosporine. Historically, immunosuppressive therapy has been the preferred option for patients unable to receive a stem cell transplant.

Nonimmunosuppressive Therapies
PROMACTA® (eltrombopag) is an effective option for SAA that’s proven to boost the production of healthy blood cells in your bone marrow.

It’s important to talk with your doctor about the treatment options that are right for you.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)
Liver problems. (continued)
Tell your health care provider right away if you have any of these signs and symptoms of liver problems: (continued)
• unusual tiredness
• right upper stomach area (abdomen) pain
• confusion
• swelling of the stomach area (abdomen)

Important Safety Information throughout this brochure and the Summary of Important Information on pages 20 to 23.
WHAT IS PROMACTA?

Adding PROMACTA® (eltrombopag) to immunosuppressive therapy has been shown to be an effective first option for patients diagnosed with SAA.

PROMACTA is the first and only once-daily oral tablet proven to boost the production of blood cells in your bone marrow.

How does your doctor know if treatment is working?

Your doctor is looking to get a “response” from treatment with PROMACTA. A response is when your blood tests show that your white blood cell, red blood cell, or platelet counts have increased.

• If your white blood cells, red blood cells, and platelets all increase above a certain level, that is called a “complete response”
• If some, but not all, of your blood cell counts increase above a specific level, that is called a “partial response”
• When complete and partial response rates are added together, that is called an “overall response”

Adding PROMACTA® to immunosuppressive therapy has been shown to be an effective first option for patients diagnosed with SAA.

To learn more about the safety of PROMACTA, please refer to the Important Safety Information throughout this brochure and the Summary of Important Information on pages 20 to 23.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

What are the possible side effects of PROMACTA?

PROMACTA may cause serious side effects, including:
• Worsening of a precancerous blood condition to a blood cancer called acute myelogenous leukemia (AML). PROMACTA is not for treatment of people with a precancerous condition called myelodysplastic syndromes (MDS). If you have MDS and receive PROMACTA, your MDS condition may worsen and become AML. If MDS worsens to become AML, you may die sooner from AML.

Be sure to talk with your doctor about your specific treatment goals.
WHY SHOULD I START WITH PROMACTA?

PROMACTA® (eltrombopag) and immunosuppressive therapy was proven in a clinical trial to show response rates.

- The average duration of response with PROMACTA + immunosuppressive therapy was just over 2 years (24.3 months)

Based on 87 patients
- 44% of patients (38 of 87) achieved a complete response
- The majority of patients (79%) experienced an overall response

MONTHS

If you are being prescribed PROMACTA, you should tell your doctor if you:
- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Be sure to tell your doctor about any other medications you may be taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

During treatment with PROMACTA, your doctor will have you go for routine bloodwork and vision monitoring.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

PROMACTA may cause serious side effects, including:

- High platelet counts and higher risk for blood clots. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA. Your risk of getting a blood clot may also be increased during treatment with PROMACTA if you have normal or low platelet counts. You may have severe problems or die from some forms of blood clots, such as clots that travel to the lungs or that cause heart attacks or strokes. Your health care provider will check your blood platelet counts and change your dose or stop PROMACTA if your platelet counts get too high. Tell your health care provider right away if you have signs and symptoms of a blood clot in the leg such as swelling, pain, or tenderness.

People with chronic liver disease may be at risk for a type of blood clot in the stomach area. Tell your health care provider right away if you have stomach area pain that may be a symptom of this type of blood clot.

If you are being prescribed PROMACTA, you should tell your doctor if you:
- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Be sure to tell your doctor about any other medications you may be taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

During treatment with PROMACTA, your doctor will have you go for routine bloodwork and vision monitoring.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

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If you are being prescribed PROMACTA, you should tell your doctor if you:
- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Be sure to tell your doctor about any other medications you may be taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

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- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Be sure to tell your doctor about any other medications you may be taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

During treatment with PROMACTA, your doctor will have you go for routine bloodwork and vision monitoring.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

PROMACTA may cause serious side effects, including:

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People with chronic liver disease may be at risk for a type of blood clot in the stomach area. Tell your health care provider right away if you have stomach area pain that may be a symptom of this type of blood clot.

If you are being prescribed PROMACTA, you should tell your doctor if you:
- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Be sure to tell your doctor about any other medications you may be taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

During treatment with PROMACTA, your doctor will have you go for routine bloodwork and vision monitoring.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

PROMACTA may cause serious side effects, including:

- High platelet counts and higher risk for blood clots. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA. Your risk of getting a blood clot may also be increased during treatment with PROMACTA if you have normal or low platelet counts. You may have severe problems or die from some forms of blood clots, such as clots that travel to the lungs or that cause heart attacks or strokes. Your health care provider will check your blood platelet counts and change your dose or stop PROMACTA if your platelet counts get too high. Tell your health care provider right away if you have signs and symptoms of a blood clot in the leg such as swelling, pain, or tenderness.

People with chronic liver disease may be at risk for a type of blood clot in the stomach area. Tell your health care provider right away if you have stomach area pain that may be a symptom of this type of blood clot.

If you are being prescribed PROMACTA, you should tell your doctor if you:
- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have had a blood clot
- have a history of cataracts
- have had surgery to remove your spleen (splenectomy)
- have bleeding problems
- are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Be sure to tell your doctor about any other medications you may be taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

During treatment with PROMACTA, your doctor will have you go for routine bloodwork and vision monitoring.
WHAT IF MY INITIAL THERAPY DOES NOT INCLUDE PROMACTA?

If your initial therapy does not work, your doctor may choose to put you on PROMACTA® (eltrombopag) alone.

A clinical study showed that PROMACTA was effective after other treatments failed.

In the study:
- **40% of patients** (17 of 43) saw an increase in their platelet levels by the third month of treatment.
- **These 17 patients remained transfusion free** for both platelets and red blood cells for a median of 6-7 months.
- **More than half of patients** (8 of 14) who responded had an increase in platelets as well as red or white blood cells. Half of those patients (4 of 8) continued to respond to PROMACTA after therapy ended.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

PROMACTA may cause serious side effects, including (continued):

- **New or worsened cataracts** (a clouding of the lens in the eye). New or worsened cataracts have happened in people taking PROMACTA. Your health care provider will check your eyes before and during your treatment with PROMACTA. Tell your health care provider about any changes in your eyesight while taking PROMACTA.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 20 to 23.
WHAT ARE THE POSSIBLE SIDE EFFECTS OF PROMACTA?

PROMACTA® (eltrombopag) may cause serious side effects, including:

- Increased risk of worsening of a precancerous blood condition called myelodysplastic syndromes (MDS) to acute myelogenous leukemia (AML)
- High platelet counts and higher risk for blood clots. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA
- Increased risk of worsening of a precancerous blood condition called myelodysplastic syndromes (MDS) to acute myelogenous leukemia (AML)
- High platelet counts and higher risk for blood clots. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA

Your doctor will check your blood platelet counts and change your dose or stop PROMACTA if your platelet counts get too high.

Tell your doctor right away if you have:

- Signs and symptoms of a blood clot in the leg, such as swelling, pain, or tenderness in your leg
- Stomach-area (abdomen) pain, nausea, vomiting, or diarrhea, as these may be symptoms of this type of blood clot
- New or worsened cataracts (a clouding of the lens in the eye). Your doctor will check your eyes before and during your treatment with PROMACTA

Tell your doctor about any changes in your eyesight while taking PROMACTA.

Important Safety Information for PROMACTA® (eltrombopag) (continued)

What should I tell my health care provider before taking PROMACTA?

Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you:

- have liver problems
- have a precancerous condition called MDS or a blood cancer
- have or have had a blood clot

Tell your doctor if you have any side effects from your treatment.
HOW SHOULD PROMACTA BE TAKEN?

Are you a morning person?
You can take PROMACTA on an empty stomach, right when you wake up. Just wait 1 hour to have a regular meal after taking PROMACTA, and avoid calcium and magnesium in food and supplements for 2 hours.

More of a night owl?
You would take PROMACTA right before you go to bed. Just make sure you haven’t had any food or supplements high in calcium or magnesium 4 hours before bed, and no meals 2 hours before bed.

Examples of calcium-rich foods containing >50 mg of calcium include dairy products (yogurt, cheese, milk, ice cream), calcium-fortified foods (orange juice, dry cereal, bread), and leafy green vegetables (collard greens, spinach).

HOW DOES PROMACTA WORK?

PROMACTA is the only therapy for SAA thought to work inside the bone marrow. PROMACTA is believed to work in the stem cell together with the body’s natural process for creating new blood cells.

Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you: (continued)

• have a history of cataracts
• have had surgery to remove your spleen (splenectomy)
FINDING THE SUPPORT YOU NEED IS EASY

Co-pay Assistance 4U
• Pay $25 per month out of pocket*
• Easy sign-up, no additional fees
• Available to most patients with commercial insurance
• Covers up to $15,000 per calendar year

Meal Planners & Dietary Guides 4U
• Tools to help you navigate the flexibility of once-daily PROMACTA. Download your personal support materials at www.PROMACTA-SAA4U.com

PROMACTA4U Patient Support Line
• Call to get additional information regarding PROMACTA® (eltrombopag), including responses to frequently asked questions

Patient Assistance Now Oncology (PANO)
• PANO was created to assist you with accessing your Novartis medicine(s)—from insurance verification to financial assistance (for eligible patients)—all through a knowledgeable and supportive call center

The following questions may help you to start a conversation with your doctor.

• How will SAA affect my life?
• What are all my treatment options?
• Which treatment option do you recommend for me? Why?
• Will I be getting more than 1 treatment?
• When should I take my medication?
• How will I know if my treatment is working?
• How often will I have blood tests?
• Are there safety factors that I should consider?

Call us at 1-800-282-7630 or visit www.PROMACTA-SAA4U.com

Important Safety Information for PROMACTA® (eltrombopag) (continued)
Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you:
(continued)
• have bleeding problems
• are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA

*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit www.CoPay.NovartisOncology.com or call 1-877-577-7756.

WARNING: PROMACTA® (eltrombopag) is indicated for the treatment of thrombocytopenia associated with chronic idiopathic or immune thrombocytopenic purpura in patients 5 years of age and older. It should not be used in patients with primary or secondary myelofibrosis, hypereosinophilic syndrome, or chronic myeloproliferative disorders, including essential thrombocytopenia. Treatment with PROMACTA may increase the risk of severe hemorrhage, including fatal cases, in patients with a history of thrombotic events or in patients with conditions that increase the risk of thrombosis. The risk of thrombotic events increases with dose and may be greater in patients with pre-existing or concurrent conditions that increase the risk of thrombosis, such as cancer and those that use medications that increase the risk of thrombosis, such as aspirin, warfarin, dabigatran, and rivaroxaban. The risk of severe hemorrhage increases in patients with a history of severe hemorrhage or in patients with concurrent conditions that increase the risk of hemorrhage. The risk of severe hemorrhage may be greater in patients with pre-existing or concurrent conditions that increase the risk of hemorrhage, such as risk factors for deep vein thrombosis or pulmonary embolism, hemostatic dysfunction, and those who receive treatment with medications that increase the risk of hemorrhage, such as aspirin, warfarin, dabigatran, and rivaroxaban. Patients should be monitored for changes in blood clotting parameters and platelet counts during treatment. Treatment with PROMACTA may increase the risk of liver disease, including hepatic decompensation, in patients with pre-existing liver disease. The risk of liver disease may be greater in patients with pre-existing or concurrent conditions that increase the risk of liver disease, such as obesity and use of medications that increase the risk of liver disease, such as aspirin, warfarin, dabigatran, and rivaroxaban. Patients should be monitored for changes in liver function tests during treatment. Treatment with PROMACTA may increase the risk of serious infections, including fatal infections, in patients with pre-existing or concurrent conditions that increase the risk of infections, such as cancer and those that use medications that increase the risk of infections, such as aspirin, warfarin, dabigatran, and rivaroxaban. The risk of serious infections may be greater in patients with pre-existing or concurrent conditions that increase the risk of infections, such as cancer and those that use medications that increase the risk of infections, such as aspirin, warfarin, dabigatran, and rivaroxaban. Patients should be monitored for changes in clinical signs and symptoms, including fever, chills, and cough, during treatment.

Use for a limited time only, as further treatment may be needed. Do not exceed the recommended daily dose.
Important Safety Information for PROMACTA® (eltrombopag) Tablets (continued)

Before you take PROMACTA, tell your health care provider about all of your medical conditions, including if you: (continued)

• are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your health care provider if you become pregnant or think you may be pregnant during treatment with PROMACTA. If you are a woman who is able to become pregnant, you must use reliable birth control (contraception) while taking PROMACTA and for at least 7 days after you stop taking PROMACTA. Talk to your health care provider about options of effective birth control methods that may be right for you during this time

• are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with PROMACTA. Talk to your health care provider about the best way to feed your baby during this time

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PROMACTA may affect the way certain medicines work. Certain other medicines may affect the way PROMACTA works.

Especially tell your health care provider if you take:

• certain medicines used to treat high cholesterol, called “statins”

• a blood thinner medicine

Certain medicines may keep PROMACTA from working correctly. Take PROMACTA at least 2 hours before or 4 hours after taking these products:

• antacids used to treat stomach ulcers or heartburn

• multivitamins, mineral supplements, or products that contain iron, calcium, aluminum, magnesium, selenium, and zinc

Ask your health care provider if you are not sure if your medicine is one that is listed above.

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

What should I avoid while taking PROMACTA?

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

The most common side effects associated with PROMACTA when used in combination with standard immunosuppressive therapy to treat severe aplastic anemia (SAA) reported more frequently than in patients with SAA when other medicines to treat SAA have not worked well enough are:

• abnormal liver function tests

• rash

• skin discoloration including darkening of skin patches (hyperpigmentation)

The most common side effects when PROMACTA is used to treat SAA when other medicines to treat SAA have not worked well enough:

• nausea
• feeling tired
• cough
• diarrhea
• headache

Laboratory tests may show abnormal changes to the cells in your bone marrow.

Tell your health care provider about any bruising or bleeding that happens while you take or after you stop taking PROMACTA.

Tell your health care provider if you have any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide.
PROMACTA is for use in people with a pre-cancerous condition called myelodysplastic syndrome (MDS), or people with low platelet counts caused by certain other medical conditions or diseases.

It is not known if PROMACTA is safe and effective when used with other antiviral medicines to treat chronic hepatitis C. PROMACTA has not been studied in people with low platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.

severe aplastic anemia (SAA) in children younger than 1 year with ITP

severe aplastic anemia (SAA) whose severe aplastic anemia (SAA) has not improved after previous treatments.

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 (abdomen) pain
– swelling of the stomach area

Before you take PROMACTA, tell your healthcare provider about all your medical conditions, including if you:

have liver problems

• have a precancerous condition called MDS or a blood cancer
• have had a blood cancer
• have a history of cataracts
• have had surgery to remove your spleen

• have bleeding problems
• are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA.
• are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your healthcare provider you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean), and your provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your healthcare provider may stop medical management with PROMACTA if you have changes in your liver function blood tests.

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

• certain medicines used to treat high cholesterol, called “statins”

• a blood thinner medicine

• certain medicines may keep PROMACTA from working well enough.

– medicines to treat chronic hepatitis C.

• medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is not used to treat adults and children 1 year of age and older with low blood platelet counts due to chronic immune thrombocytopenia (ITP), when other medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is also used to treat people with:

• low blood platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.

• severe aplastic anemia (SAA) in combination with other medicines to treat SAA, as the first treatment for adults and children 2 years of age and older.

• severe aplastic anemia (SAA) when other medicines to treat SAA have not worked well enough.

PROMACTA is used to reduce the risk of bleeding for people with severe thrombocytopenia (low blood platelets). People with severe thrombocytopenia are at high risk for easy bruising or bleeding. These people include:

• people with low platelet counts caused by certain other medical conditions or diseases.

• people with low platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.

• people with other medical conditions or diseases.

• people with liver problems

it is not known if PROMACTA is safe and effective when used with other antiviral medicines to treat chronic hepatitis C.

It is not known if PROMACTA is safe and effective in children:

• younger than 1 year with ITP
• with low blood platelet counts due to chronic hepatitis C
• whose severe aplastic anemia (SAA) has not improved after previous treatments.

Before you take PROMACTA, tell your healthcare provider if:

• you have liver problems

• you have had a blood cancer

• you have had surgery to remove your spleen

• you have bleeding problems

• you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA.

• you are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your healthcare provider you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean), and your provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your healthcare provider may stop medical management with PROMACTA if you have changes in your liver function blood tests.

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 (abdomen) pain
– swelling of the stomach area

Before you take PROMACTA, tell your healthcare provider about all your medical conditions, including if you:

• have liver problems

• have a precancerous condition called MDS or a blood cancer

• have had a blood cancer

• have a history of cataracts

• have had surgery to remove your spleen

• have bleeding problems

• are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA.

• are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with PROMACTA.

• females are able to become pregnant, should use effective birth control (contraception) during treatment with PROMACTA. Your provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your healthcare provider may stop medical management with PROMACTA if you have changes in your liver function blood tests.

Tell your healthcare provider if you take:

• certain medicines used to treat high cholesterol, called “statins”

• a blood thinner medicine

• certain medicines may keep PROMACTA from working well enough.

– medicines to treat chronic hepatitis C.

• medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is not used to treat adults and children 1 year of age and older with low blood platelet counts due to chronic immune thrombocytopenia (ITP), when other medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is also used to treat people with:

• low blood platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.

• severe aplastic anemia (SAA) in combination with other medicines to treat SAA, as the first treatment for adults and children 2 years of age and older.

• severe aplastic anemia (SAA) when other medicines to treat SAA have not worked well enough.

PROMACTA is used to reduce the risk of bleeding for people with severe thrombocytopenia (low blood platelets). People with severe thrombocytopenia are at high risk for easy bruising or bleeding. These people include:

• people with low platelet counts caused by certain other medical conditions or diseases.

• people with low platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.

• people with other medical conditions or diseases.

• people with liver problems

it is not known if PROMACTA is safe and effective when used with other antiviral medicines to treat chronic hepatitis C.

It is not known if PROMACTA is safe and effective in children:

• younger than 1 year with ITP
• with low blood platelet counts due to chronic hepatitis C
• whose severe aplastic anemia (SAA) has not improved after previous treatments.

Before you take PROMACTA, tell your healthcare provider if:

• you have liver problems

• you have had a blood cancer

• you have a history of cataracts

• you have had surgery to remove your spleen

• you have bleeding problems

• you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA.

• you are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your healthcare provider you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean), and your provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your healthcare provider may stop medical management with PROMACTA if you have changes in your liver function blood tests.

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 (abdomen) pain
– swelling of the stomach area

Before you take PROMACTA, tell your healthcare provider about all your medical conditions, including if you:

• have liver problems

• have a precancerous condition called MDS or a blood cancer

• have had a blood cancer

• have a history of cataracts

• have had surgery to remove your spleen (splenectomy)

• have bleeding problems

• are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean). You may need a lower dose of PROMACTA.

• are pregnant or plan to become pregnant. It is not known if PROMACTA will harm an unborn baby. Tell your healthcare provider you are of Asian ancestry (such as Chinese, Japanese, Taiwanese, or Korean), and your provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your healthcare provider may stop medical management with PROMACTA if you have changes in your liver function blood tests.

Tell your healthcare provider if you take:

• certain medicines used to treat high cholesterol, called “statins”

• a blood thinner medicine

• certain medicines may keep PROMACTA from working well enough.

– medicines to treat chronic hepatitis C.

• medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is not used to treat adults and children 1 year of age and older with low blood platelet counts due to chronic immune thrombocytopenia (ITP), when other medicines to treat ITP or surgery to remove the spleen have not worked well enough.

PROMACTA is also used to treat people with:

• low blood platelet counts due to chronic hepatitis C virus (HCV) infection before and during treatment with interferon.

• severe aplastic anemia (SAA) in combination with other medicines to treat SAA, as the first treatment for adults and children 2 years of age and older.

• severe aplastic anemia (SAA) when other medicines to treat SAA have not worked well enough.

PROMACTA is used to reduce the risk of bleeding for people with severe thrombocytopenia (low blood platelets). People with severe thrombocytopenia are at high risk for easy bruising or bleeding. These people include:

• people with low platelet counts caused by certain other medical conditions or diseases.
Summary of Important Information (continued)

- If you miss a dose of PROMACTA, wait and take your next scheduled dose. Do not take more than 1 dose of PROMACTA in 1 day.
- If you take too much PROMACTA, you may have a higher risk of serious side effects. Call your healthcare provider right away.
- Your healthcare provider will check your platelet count during your treatment with PROMACTA and change your dose of PROMACTA as needed.
- Tell your healthcare provider about any bruising or bleeding that happens while you take and after you stop taking PROMACTA.
- If you have SAA, your healthcare provider may do tests to monitor your bone marrow during treatment with PROMACTA.

What are the possible side effects of PROMACTA?

You may have severe problems or die from some forms of blood clots, such as clots that travel to the lungs or that cause heart attacks or strokes. Your healthcare provider will check your blood platelet counts, and change your dose or stop PROMACTA if your platelet counts get too high. Tell your healthcare provider right away if you have signs and symptoms of a blood clot in the leg, such as swelling, pain, or tenderness in your leg. People with chronic liver disease may be at risk for a type of blood clot in the stomach area (abdomen). Tell your healthcare provider right away if you have stomach-area (abdomen) pain, nausea, vomiting, or diarrhea as these may be symptoms of this type of blood clot.

The most common side effects of PROMACTA in adults and children include:
- low red blood cell count (anemia)
- nausea
- fever
- abnormal liver function tests
- cough
- tiredness
- headache
- diarrhea

Laboratory tests may show abnormal changes to the cells in your bone marrow. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of PROMACTA. For more information, ask your healthcare provider or pharmacist.

How should I store PROMACTA tablets and PROMACTA for oral suspension?

Tablets:
- Store PROMACTA tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep PROMACTA in the bottle given to you.

For oral suspension:
- Store PROMACTA for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- After mixing, PROMACTA should be taken right away but may be stored for no more than 30 minutes between 68°F to 77°F (20°C to 25°C). Throw away (discard) the mixture if not used within 30 minutes.

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

The risk information provided here is not comprehensive. To learn more, talk about PROMACTA with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at www.PROMACTA.com or 1-888-669-6682.

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- abnormal liver function tests
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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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ASK YOUR DOCTOR IF PROMACTA IS RIGHT FOR YOU

PROMACTA® (eltrombopag) is approved for use in SAA:

Right From the Start

PROMACTA + Immunosuppressive Therapy

When Other Therapies Have Failed

PROMACTA Alone

For the treatment of your SAA, turn to PROMACTA for help.

Approved Uses for PROMACTA® (eltrombopag) Tablets

PROMACTA is a prescription medicine used to treat people with severe aplastic anemia (SAA) in combination with standard immunosuppressive therapy as the first treatment for adults and children 2 years of age and older. PROMACTA is also used to treat your SAA when other medicines have not worked well enough.

PROMACTA is not used to make platelet counts normal.

PROMACTA is for treatment of certain people with low platelet counts caused by chronic immune thrombocytopenia (ITP), chronic hepatitis C virus (HCV), or SAA, not for a precancerous condition called myelodysplastic syndromes (MDS) or low platelet counts caused by other conditions or diseases.

It is not known if PROMACTA is safe and effective in children with chronic HCV or previously treated SAA, in children younger than 1 year with ITP, or children younger than 2 years when used in combination with standard immunosuppressive therapy as the first treatment for SAA.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 20 to 23.

Call us at 1-800-282-7630 or visit www.PROMACTA-SAA4U.com to learn more!