For people with severe aplastic anemia

Take charge of your treatment journey

Approved Uses and Important Safety Information

Approved Uses for PROMACTA® (eltrombopag)

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 persistent or 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)

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. Your health care provider will do blood tests to check your liver function before you start taking PROMACTA and during treatment. Your health care provider may stop your treatment with PROMACTA if you have changes in your liver function blood tests.

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

Patient portrayal.
SAA, severe aplastic anemia.

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

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

Tell your health care 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
- confusion
- swelling of the stomach area (abdomen)

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

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

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 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.

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12.5mg, 25mg oral suspension

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 in 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.

Nonimmunosuppressive Therapies
PROMACTA is an option for SAA that's been proven in clinical studies to boost the production of healthy blood cells in bone marrow.

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.

Bone Marrow Stem Cell Transplantation
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.

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

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

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

What are the possible side effects of PROMACTA? (continued)

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

- **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

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Patient portrayal.

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12.5mg, 25mg oral suspension

How does your doctor know if PROMACTA is working?

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

Your doctor is looking for a **"response"** from treatment with PROMACTA. A response is when your blood tests show that your white blood cell, red blood cell, and/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"**
- If you start responding to therapy, your doctor will monitor how long your response lasts—that is called **"duration of response"**

To learn about the safety of PROMACTA, see Important Safety Information throughout this brochure and Summary of Important Information here.

PROMACTA is the **first and only** TPO-RA treatment for SAA proven to **boost the production of blood cells in your bone marrow**.

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

What are the possible side effects of PROMACTA? (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 here.

Patient portrayal.
TPO-RA, thrombopoietin receptor agonist.

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PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

Why should I start with PROMACTA?

PROMACTA + immunosuppressive therapy was proven in a clinical trial to show response.

Based on 87 patients

- **44%** of patients achieved a **complete response**
- The **majority** of patients (79%) experienced an **overall response**

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

  This means that half of patients who responded had a duration of response of more than 24.3 months and half had less than that

Median duration of response

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 or 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.

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

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

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12.5mg, 25mg oral suspension

What if my first therapy does not include PROMACTA?

If your first therapy does not work, your doctor may choose to put you on PROMACTA 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 platelets**, **red blood cells**, and/or white blood cells 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** and continued to the extension phase of the trial **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) (continued)

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

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12.5mg, 25mg oral suspension

What are the possible side effects of PROMACTA?

PROMACTA may cause serious side effects, including:

- Liver problems. PROMACTA may increase your risk of liver problems that may be severe and possibly life-threatening. Your health care provider will do blood tests to check your liver function before you start taking PROMACTA and during treatment. Your health care provider may stop your treatment with PROMACTA if you have changes in your liver function blood tests
- 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

  People with chronic liver disease may be at risk for a type of blood clot in the stomach area (abdomen)

  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. Your risk of getting a blood clot is increased if your platelet count is too high during treatment with PROMACTA

  — 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

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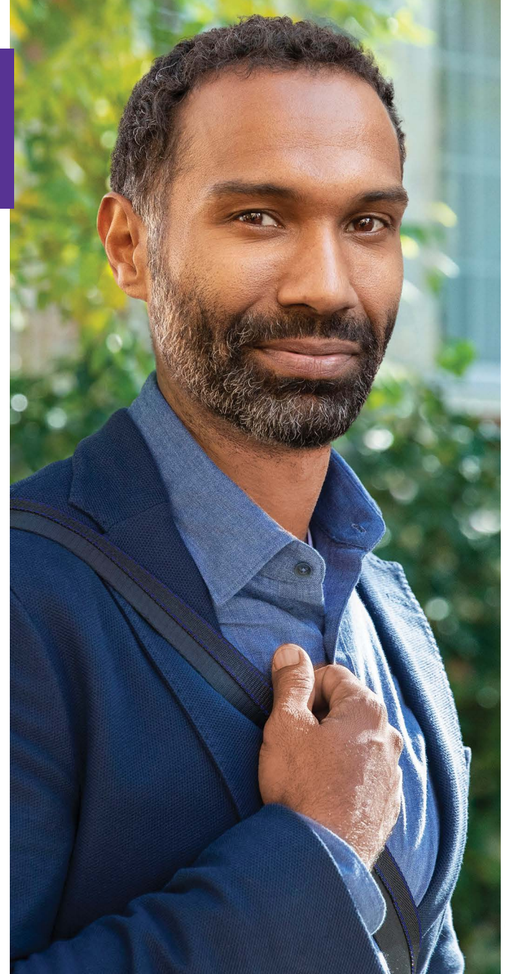
Please see Important Safety Information throughout this brochure and the Summary of Important Information here.



Patient portrayal.

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

Tell your doctor if you have any side effects from your treatment.

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

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

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PROMACTA® (eltrombopag)

12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

How should PROMACTA be taken?

PROMACTA is a once-daily oral treatment that fits into your daily routine.
It is available as a tablet or in an oral suspension for patients who can't swallow a pill.

When taking PROMACTA, here are 2 important things to remember:

1. PROMACTA can be taken without a meal or with a meal low in calcium (50 mg or less)
2. PROMACTA should be taken 2 hours before or 4 hours after taking medications like antacids, mineral supplements, or foods that are high in calcium (greater than 50 mg)

Certain medications and supplements may keep PROMACTA from working correctly. Take PROMACTA at least 2 hours before or 4 hours after taking products that contain iron, calcium, aluminum, magnesium, selenium, or zinc

Be sure to talk to your doctor if you have any questions about taking PROMACTA.

Take PROMACTA without a meal or with a meal low in calcium (50 mg or less) and at least 2 hours before or 4 hours after eating calcium-rich foods, such as:

- **Dairy products** (yogurt, cheese, milk, ice cream)
- **Calcium-fortified foods** (orange juice, dry cereal, white bread)
- **Leafy green vegetables** (collard greens, spinach)
- **Certain fruits** (oranges, dried figs)

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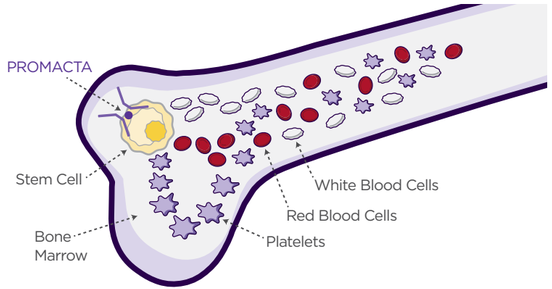
Click **here** to learn more about how you can fit PROMACTA into your lifestyle.

Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

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.

Blood Cell Production



When your bone marrow is not producing the amount of blood cells your body needs, **PROMACTA may help increase the production of:**

- Red blood cells
- White blood cells
- Platelets

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

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

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PROMACTA® (eltrombopag)
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12.5mg, 25mg oral suspension

Access to PROMACTA

Patient Assistance Now Oncology (PANO)

- Our PANO support center offers **a single point of contact from Novartis** to help guide you through getting access to the medicine prescribed by your doctor—from **insurance verification to information about financial assistance**

Free Trial Program

- If you have been prescribed PROMACTA, **you may be eligible to receive a free 14-day supply to help you begin therapy via mail**. You will need to complete a Patient Assistance Now Oncology Service Request Form (PANO SRF) to see if you qualify (for FDA-approved uses/indications only)

If you are looking for insurance coverage information, support programs, and/or free product trials, PANO may be able to help. To enroll now, call **1-800-282-7630** or visit **Novartis Patient Support**

FDA, US Food and Drug Administration.

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

Universal Co-pay Program

You may be eligible for immediate co-pay savings on your next prescription of PROMACTA.

- Eligible patients with private insurance may pay **$0 per month**
- Novartis will pay the remaining co-pay, up to $15,000 per calendar year, per product

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 Copay.NovartisOncology.com or call 1-877-577-7756.

To find out if you are eligible for the Novartis Oncology Universal Co-pay Program today, text **SAVINGS** to **34039**, call **1-877-577-7756**, or visit **Copay.NovartisOncology.com**.

Low to no co-pay for Medicare and commercial patients.

- 70% pay $10 or less—and 59% have a **$0 co-pay***

*Medicare patients are not eligible for the Universal Co-pay Program. The information about Medicare patients' co-pay is a function of the Medicare benefit design applicable to the product.

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12.5mg, 25mg oral suspension

Patient portrayal.

Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

Novartis Patient Assistance Foundation (NPAF)

The Novartis Patient Assistance Foundation, Inc., may help provide access to Novartis medicines if you are experiencing financial hardship and/or have no third-party insurance coverage. You may be eligible to receive your Novartis medicine(s) for free.

To be eligible for NPAF assistance, you must:

- Be a US resident
- Meet certain income requirements
- Have limited or no prescription coverage*

If you are seeking NPAF assistance for the first time, you must submit the Patient Assistance Now Oncology Service Request Form (PANO SRF).

To learn more: Call NPAF at **1-800-277-2254** or visit **PAP.Novartis.com**.

*Exceptions exist for individuals with limited prescription coverage. Please be advised that access to the medicines distributed through the Novartis Patient Assistance Foundation, Inc., is free of charge to all eligible patients.

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12.5mg, 25mg oral suspension

Take an active role in your treatment

Working closely with your health care team is the best way to get the care you need. Use the following questions to start a conversation with your doctor. Working together, you can manage and plan for the future.

- 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 **us.promacta.com**.

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

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

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

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

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

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

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 are:
- 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**.

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PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

Summary of Important Information for PROMACTA® (eltrombopag)

What is PROMACTA?

PROMACTA is a prescription medicine used to treat adults and children 1 year of age and older with low blood platelet counts due to persistent or 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 try to raise platelet counts in order to lower your risk for bleeding.

PROMACTA is not used to make platelet counts normal.

PROMACTA is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS) or in 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.

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 SAA has not improved after previous treatments
- younger than 2 years when used in combination with other medicines to treat SAA as the first treatment for SAA

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

PROMACTA can cause serious side effects, including:

Liver problems:

- If you have chronic hepatitis C virus and take PROMACTA with interferon and ribavirin treatment, PROMACTA may increase your risk of liver problems. If your health care provider tells you to stop your treatment with interferon and ribavirin, you will also need to stop taking PROMACTA
- PROMACTA may increase your risk of liver problems that may be severe and possibly life-threatening. Your health care provider will do blood tests to check your liver function before you start taking PROMACTA and during your treatment. Your health care provider may stop your treatment with PROMACTA if you have changes in your liver function blood tests

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Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

Tell your health care 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
- confusion
- swelling of the stomach area (abdomen)

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
- 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 health care provider if you become pregnant or think you may be pregnant during treatment with PROMACTA
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with PROMACTA and for at least 7 days after stopping treatment with PROMACTA. Talk to your health care provider about birth control methods that may be right for you during this time
- are breastfeeding or plan to breastfeed. You should not breastfeed during your 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:

- antacid medicine used to treat stomach ulcers or heartburn
- multivitamins or products that contain iron, calcium, aluminum, magnesium, selenium, and zinc which may be found in mineral supplements

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.

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PROMACTA® (eltrombopag)

12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

Summary of Important Information for PROMACTA® (eltrombopag) (continued)

How should I take PROMACTA?

- Take PROMACTA exactly as your health care provider tells you to take it. Your health care provider will prescribe the dose of PROMACTA tablets or PROMACTA for oral suspension that is right for you
- If your health care provider prescribes PROMACTA tablets, take PROMACTA tablets whole. **Do not split, chew, or crush PROMACTA tablets and do not mix with food or liquids**
- If your health care provider prescribes PROMACTA for oral suspension, see the **"Instructions for Use"** that comes with your medicine for instructions on how to correctly mix and take a dose of PROMACTA
- Use a new single-use oral dosing syringe to prepare each dose of PROMACTA for oral suspension.
  Do not reuse the oral dosing syringe
- **Do not** stop taking PROMACTA without talking with your health care provider first. Do not change your dose or schedule for taking PROMACTA unless your health care provider tells you to change it
- Take PROMACTA without a meal or with a meal low in calcium (50 mg or less) and at least 2 hours before or 4 hours after eating calcium-rich foods, such as dairy products, calcium-fortified juices, and certain fruits and vegetables
- 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 health care provider right away
- Your health care provider will check your platelet count during your treatment with PROMACTA and change your dose of PROMACTA as needed
- Tell your health care provider about any bruising or bleeding that happens while you take and after you stop taking PROMACTA
- If you have SAA, your health care provider may do tests to monitor your bone marrow during treatment with PROMACTA

What should I avoid while taking PROMACTA?

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

What are the possible side effects of PROMACTA?

PROMACTA may cause serious side effects, including:

- See **"What is the most important information I should know about PROMACTA?"**
- **Increased risk of worsening of a precancerous blood condition called myelodysplastic syndromes (MDS) to acute myelogenous leukemia (AML).** PROMACTA is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS). See **"What is PROMACTA?"** If you have MDS and receive PROMACTA, you have an increased risk that your MDS condition may worsen and become a blood cancer called AML. If your MDS worsens to become AML, you may have an increased risk of death from 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 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 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 health care 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
- **New or worsened cataracts (a clouding of the lens in the eye).** New or worsened cataracts can happen 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

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 health care 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 health care provider or pharmacist.

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

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 health care provider or pharmacist. The FDA-approved product labeling can be found at www.PROMACTA.com or 1-888-669-6682.

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PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

Please see Important Safety Information throughout this brochure and the Summary of Important Information here.

Patient portrayal.

Ask your doctor if PROMACTA is right for you

PROMACTA is approved for use in SAA:

Right From the Start
PROMACTA + Immunosuppressive Therapy

When Other Therapies Have Failed
PROMACTA (Taken Alone)

PROMACTA may help treat your SAA

Call us at **1-800-282-7630**
or click **here** to learn more!

Important Safety Information for PROMACTA® (eltrombopag)

The most common side effects of PROMACTA include low red blood cell count (anemia), nausea, fever, abnormal liver function tests, cough, tiredness, headache, and diarrhea.

Please see Important Safety Information throughout this brochure and the Summary of Important Information.

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NOVARTIS

PROMACTA® (eltrombopag)
12.5mg, 25mg, 50mg, 75mg tablets
12.5mg, 25mg oral suspension

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