

**This Prescriber Enrollment Form must be completed before you can prescribe PROMACTA. PROMACTA is available only through a mandatory restricted distribution program called PROMACTA CARES.**

**I understand that PROMACTA<sup>®</sup> (eltrombopag) is only available through PROMACTA CARES and I agree to comply with the following program requirements:**

- I have read the full Prescribing Information for PROMACTA.
- I understand that PROMACTA is approved for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- I understand that PROMACTA is only indicated for use in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk of bleeding.
- I understand that PROMACTA should not be used in an attempt to normalize platelet counts.
- I understand that PROMACTA is not indicated for the treatment of thrombocytopenia due to causes of thrombocytopenia (e.g., myelodysplasia or chemotherapy) other than chronic ITP.
- I understand the following risks are associated with PROMACTA:
  - PROMACTA administration may cause hepatotoxicity. If a patient develops serious liver function test abnormalities, I should discontinue treatment with PROMACTA.
  - PROMACTA increases the risk for development or progression of reticulin fibers within the bone marrow. If the patient develops new or worsening morphological abnormalities or cytopenia(s), I should discontinue treatment with PROMACTA and consider a bone marrow biopsy, including staining for fibrosis.
  - Discontinuation of PROMACTA may result in thrombocytopenia of greater severity than was present prior to therapy with PROMACTA. Serious hemorrhagic events requiring the use of supportive ITP medications occurred in clinical studies within one month following the discontinuation of PROMACTA.
  - Thrombotic/thromboembolic complications may result from excessive increases in platelet counts.
  - Stimulation by PROMACTA of the TPO receptor on the surface of hematopoietic cells may increase the risk for hematologic malignancies, especially in patients with myelodysplastic syndrome.
- I understand that each patient should be monitored as follows to assure safe use of PROMACTA:
  - Complete Blood Count:**
    - Monitor CBCs, including platelet counts and peripheral blood smears, prior to initiation, and weekly during the dose adjustment phase of therapy with PROMACTA.
    - Monitor CBCs, including platelet counts and peripheral blood smears, monthly following establishment of a stable dose of PROMACTA.
    - If PROMACTA is discontinued, obtain CBCs, including platelet counts weekly for at least 4 weeks after discontinuation.
  - Liver Tests:**
    - Monitor serum liver tests (ALT, AST, bilirubin) prior to initiation of PROMACTA.
    - Monitor serum liver tests (ALT, AST, bilirubin) every 2 weeks during the dose adjustment phase and then monthly following establishment of a stable dose of PROMACTA.
    - If abnormal levels are detected, monitor serum liver tests within 3 to 5 days, then weekly until the abnormality(ies) resolves, stabilizes, or returns to baseline levels.
    - Discontinue PROMACTA if ALT levels increase to 3X the upper limit of normal [ULN] and are:
      - Progressive, or
      - Persistent for 4 weeks, or
      - Accompanied by increased direct bilirubin, or
      - Accompanied by clinical symptoms of liver injury or evidence of hepatic decompensation.
- Reinitiating treatment with PROMACTA after discontinuation due to hepatotoxicity is not recommended and should be considered only with close medical supervision and under exceptional circumstances where the potential benefit outweighs the risk. If liver test abnormalities persist, worsen or recur, then permanently discontinue PROMACTA.

*continued*

- I understand that I am required to complete this Prescriber Enrollment Form to enroll (once) myself in PROMACTA CARES.
- I will enroll each patient by assisting in the completion of the PROMACTA CARES Patient Enrollment Form and completing the PROMACTA CARES Patient Baseline Form at the time of enrollment or within 30 days of patient enrollment. I understand that baseline data is only to be used to assess for risk factors for adverse events and to evaluate the long-term safety of PROMACTA. I will obtain the patient's signature on the Patient Enrollment Form, place the original signed form in the patient's medical record, send a copy to PROMACTA CARES, and give a copy to the patient.
- I will provide each patient with the Medication Guide for PROMACTA prior to providing each prescription and counsel each patient on the risks and benefits of PROMACTA.
- I will evaluate the patient's status every 6 months to determine whether the patient should continue PROMACTA, and if so, authorize treatment for another 6 months.
- I will notify PROMACTA CARES when a patient discontinues PROMACTA by completing the Patient Discontinuation and Post-Therapy Follow-up Form for PROMACTA CARES at the time of discontinuation of PROMACTA and complete the same again 3 months later.
- I will promptly report to PROMACTA CARES any adverse event occurring in the course of the use of the drug as described in the Medical and Reauthorization Form for PROMACTA CARES.
- I understand that it is my responsibility to ensure appropriate transition of patients to the outpatient setting if my patient(s) is initiated on PROMACTA as an inpatient.
- I understand GlaxoSmithKline (GSK), its agents, and contractors may contact me via phone, mail, or e-mail to assess the effectiveness of the program requirements for PROMACTA CARES.
- I understand that if I fail to comply with the requirements of PROMACTA CARES, I may no longer be able to participate in PROMACTA CARES.
- I further understand that I have sole responsibility for all medical judgments and treatments, and have sole responsibility, prior to administration of PROMACTA, to counsel each patient on the risks of PROMACTA, and to provide each patient with all necessary warnings concerning PROMACTA.

Prescriber Name (Please Print): \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

PRESCRIBER	<b>Prescriber Information (Please Print)</b>	
	Full Name: _____	Site Name: _____
	Address: _____	
	City: _____	State: _____ ZIP: _____
	State License #: _____	State Issued: _____ DEA#: _____ NPI # (optional) _____
	Specialty: _____	Phone: _____ FAX: _____ E-mail: _____
	Indicate your primary treatment setting:	
	<input type="checkbox"/> Inpatient	
	<input type="checkbox"/> Outpatient facility not affiliated with an institution/hospital	
	<input type="checkbox"/> Outpatient facility with a dispensing clinic	
<input type="checkbox"/> Outpatient facility affiliated with an institution/hospital		
Should you wish to dispense from your Dispensing Clinic you must also complete the Hospital Pharmacy or Dispensing Clinic Authorization Form.		

**Please fax this completed form to PROMACTA CARES at 1-866-765-0920.**

**You will receive enrollment confirmation via fax within 1 hour during 8:30AM-8:00PM M-F Eastern Standard Time.**

**For questions regarding PROMACTA CARES, call 1-877-9-PROMACTA (1-877-977-6622).**