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**IMPORTANT PRESCRIBING INFORMATION**

**Date:** December 6, 2011

**Subject:** • **PROMACTA REMS Program: Elimination of Prescriber, Pharmacy, and Patient Enrollment requirements to prescribe, dispense and receive PROMACTA**  
• **Serious risks associated with PROMACTA**

Dear Healthcare Professional:

**As of December 6, 2011:**

- **Healthcare Professionals/Prescribers** – No longer need to be enrolled to prescribe PROMACTA or complete and submit safety forms
- **Pharmacies** - No longer need to enroll. Pharmacists no longer need to verify prescriber and patient enrollment before dispensing PROMACTA
- **Patients** - No longer need to be enrolled in order to receive PROMACTA

Any prescriber or hospital will be able to order PROMACTA without enrolling either themselves or patients.

**Why are the REMS restricted distribution requirements being eliminated?**

The restrictive elements of the REMS included enrollment of prescribers, patients, and pharmacies to assist in collecting long-term safety information. Upon further review, FDA and GSK have determined that the safety information collected through the REMS, which is based on individual case safety reports, is inherently confounded by underlying medical conditions in the treated population and thus cannot be used to determine the precise role of PROMACTA in the development of the adverse events. Based in part on this determination and the data submitted from clinical trials, FDA and GSK have concluded that the restrictive elements of the REMS can be eliminated. For this reason, enrollment of prescribers, patients, and pharmacies, and mandatory collection of safety data is no longer required.

**What has changed?**

*Prescribers*

- No longer need to enroll in PROMACTA CARES
- No longer need to enroll patients in PROMACTA CARES
- No longer need to complete and submit the enrollment, baseline, medical and reauthorization, and discontinuation and post-therapy forms

Prescribers should inform their patients previously or currently enrolled in PROMACTA CARES of the elimination of this program.

*Pharmacists*

- No longer need to complete initial pharmacy enrollment forms and training
- No longer need to confirm prescriber and patient enrollment in PROMACTA CARES with each prescription/refill

- No longer need to maintain and submit a record verification Inventory Tracking Log
- No longer need to undergo periodic audits to ensure PROMACTA is dispensed in accordance with program requirements

### Ordering PROMACTA

- There are no restrictions on ordering PROMACTA
- **There is no change to the ordering process for PROMACTA.** PROMACTA will continue to be available through specialty pharmacies, hospital pharmacies and dispensing clinics. GSK will continue to offer the patient assistance programs and reimbursement support programs through CARES by GSK ([www.CARESbyGSK.com](http://www.CARESbyGSK.com))

## What has NOT changed?

### Risks

#### PROMACTA is associated with serious risks including:

- **Hepatotoxicity:** PROMACTA may cause hepatotoxicity.
  - Measure serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin prior to initiation of PROMACTA, every 2 weeks during the dose adjustment phase, and monthly following establishment of a stable dose. If bilirubin is elevated, perform fractionation
  - Evaluate abnormal serum liver tests with repeat testing within 3 to 5 days. If the abnormalities are confirmed, monitor serum liver tests weekly until the abnormality(ies) resolve, stabilize, or return to baseline levels
  - Discontinue PROMACTA if ALT levels increase to  $\geq 3X$  the upper limit of normal (ULN) and are:
    - progressive, or
    - persistent for  $\geq 4$  weeks, or
    - accompanied by increased direct bilirubin, or
    - accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation.
- **Reticulin fiber deposition:** PROMACTA may increase the risk for development or progression of reticulin fiber deposition within the bone marrow. Monitor peripheral blood for signs of marrow fibrosis
- **Thrombosis/Thromboembolism** may result from increases in platelet counts with PROMACTA. Portal vein thrombosis has been reported in patients with chronic liver disease receiving PROMACTA
- **Hematologic Malignancies:** PROMACTA may increase the risk for hematologic malignancies. PROMACTA is not indicated for the treatment of thrombocytopenia due to diseases or treatments that cause thrombocytopenia (e.g., myelodysplasia or chemotherapy) other than chronic ITP

### Indication

PROMACTA is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

- PROMACTA should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding
- PROMACTA should not be used in an attempt to normalize platelet counts

Please see Prescribing Information for complete description of safety information, including BOXED WARNING.

#### *Prescribers*

- Continue to discuss the benefits and risks of PROMACTA with your patients
- Select the appropriate patients to receive PROMACTA in accordance with the approved prescribing information
- Monitor your patients as specified in the Prescribing Information
- Continue to report adverse drug reactions to GSK

#### *Pharmacists*

- Continue to provide the Medication Guide with each prescription/refill
- Continue to report adverse drug reactions to GSK

#### **What about records I collected for the PROMACTA CARES Program?**

Enrolled prescribers and pharmacies should maintain patient and PROMACTA CARES Program records in accordance with state and local records retention requirements.

#### **What if I have safety information to submit?**

- GSK will continue to accept safety information for enrolled patients for an additional 4 weeks, safety information can be faxed to 866-765-0920 or provided by phone at call 1-877-977-6622
- After January 3, 2012, report SUSPECTED ADVERSE REACTIONS to GSK at 1-888-825-5249 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

GSK will not send any additional reminders to prompt safety data collection. This letter serves as the final request for information.

#### **What will GSK do with the patient health information already collected?**

Patient health information and data collected throughout the PROMACTA CARES Program continues to be protected and will be disclosed only for the purposes described in the patient enrollment form.

#### **Further Information**

Should you require additional information about PROMACTA please refer to the Prescribing Information found at [http://us.gsk.com/products/assets/us\\_promacta.pdf](http://us.gsk.com/products/assets/us_promacta.pdf) or contact GSK Customer Response Center at 1-888-825-5249.

Sincerely,



Manuel Aivado, MD  
Director, Global Clinical Development Oncology  
GlaxoSmithKline

#### **Reference**

Prescribing Information for PROMACTA December, 2011.