Generic Name:
Romiplastim; eltrombopag
Trade Name:
Nplate; Promacta
Company:
Amgen; GlaxoSmithKline
Notes:

FDA today announced that health professionals and facilities, including pharmacists and pharmacies, no longer need to be registered in REMS programs to prescribe and/or dispense these agents. Nplate and Promacta were originally approved in 2008 with several restrictions designed to maximize the benefits and minimize the risks of therapy in the target population.

Specific FDA actions are as follows:

- Health professionals, hospitals, specialty care facilities, and patients are no longer required to be enrolled in the Nplate NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program or the Promacta CARES Program to prescribe, dispense, or receive these products. Health professionals also will no longer be required to complete periodic safety forms for patients receiving Nplate or Promacta.
- Pharmacies/pharmacists no longer are required to enroll in the Promacta CARES Program or verify prescriber and patient enrollment before dispensing Promacta.
- The modified REMS programs will include a communication plan that will inform health professionals about the changes to the REMS and the safety risks associated with each product.

FDA said that it has monitored specific safety risks related to both products since their approval, including bone marrow changes of collagen deposition (reticulin), higher risk for blood clots, increased risk of development of other hematologic malignancies resulting from the stimulation of bone marrow cells, worsening low blood platelet count, and the risk of bleeding shortly after discontinuing the drugs. FDA has decided that the long-term safety of Nplate and Promacta can be evaluated based on ongoing clinical trials, postapproval studies agreed to by both companies, and adverse event reports submitted to the agency.

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of adult patients with chronic immune thrombocytopenia (ITP) who have not responded adequately to corticosteroids, immunoglobulins, or splenectomy