

## **FDA NEWS RELEASE**

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### **FDA announces changes to risk strategy requirements for 2 drugs to treat low platelet counts**

*Includes labeling revisions for both drugs*

The approval of changes to the Risk Evaluation and Mitigation Strategies (REMS) for both Nplate (romiplostim) and Promacta (eltrombopag) was announced by the U.S. Food and Drug Administration.

An FDA-initiated review of the current information has determined that while safety risks for both Nplate and Promacta still exist, certain restrictive requirements of the REMS programs are no longer necessary to ensure that the benefits of the drugs outweigh their risks. FDA will continue to monitor these drugs for safety risks.

The agency has concluded that the long-term safety of Nplate and Promacta can be evaluated based on ongoing clinical trials, post-approval studies agreed to by both companies, and adverse event reports submitted to FDA.

Major changes to the REMS for both products include:

- Health care 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. Healthcare 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 care professionals about the changes to the REMS and the safety risks associated with each product.

Healthcare professionals and patients should also be aware that:

- The warnings and precautions sections of the product labels have been updated to reflect the current understanding of the safety of the drugs.

- Healthcare professionals should continue to refer to the drug prescribing information for the latest recommendations on prescribing Nplate and Promacta and report adverse events for both products to the FDA MedWatch program (<http://www.fda.gov/Safety/MedWatch/default.htm>).
- Patients should read the Medication Guide that they receive with their Nplate or Promacta prescription and contact their healthcare professional regarding any questions or concerns.

"REMS continue to be vital tools for the agency to employ as we work with companies to address the serious risks associated with drugs and monitor their appropriate and safe use in various health care settings," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "The agency remains committed to exercising a flexible and responsible regulatory approach that ensures REMS programs are being effectively and efficiently used and not resulting in an unnecessary burden on health care professionals and patients."

Nplate and Promacta were both approved in 2008 to treat adult patients with chronic immune thrombocytopenia (ITP), who have not responded adequately to corticosteroids, immunoglobulins, or to the removal of their spleen (splenectomy).

ITP is a rare blood disorder that results in a low number of platelets, the blood components that help with clotting. Low numbers of platelets can lead to serious bleeding. The treatments work by stimulating the bone marrow to produce needed platelets.

At the time of approval, experience with both drugs was limited, and safety concerns led to a decision to require a REMS that included restricted distribution requirements for each drug to ensure that the benefits of the drugs outweighed their risks. The restricted distribution requirements called for health care professionals, pharmacies, hospitals, specialty care facilities and patients to enroll in a special access program to prescribe, dispense or receive the drugs.

Since the approval of Nplate and Promacta, the FDA has continued to monitor specific safety risks related to both products including bone marrow changes of collagen deposition (reticulin), higher risk for blood clots, increased risk of development of other blood-related cancers (hematological malignancies) resulting from the stimulation of bone marrow cells, worsening low blood platelet count and the risk of bleeding shortly after discontinuing the drugs. Promacta may also cause liver injury.

Other side effects seen in patients treated with Nplate include: headaches, dizziness, trouble falling or staying asleep (insomnia), pain in the stomach (abdominal), shoulder, joints (arthralgia) and muscle (myalgia), upset stomach (dyspepsia), and tingling or numbness in the skin (paresthesia).

Promacta has been associated with the following side effects: nausea, diarrhea, upper respiratory tract infection, vomiting, rash, flu (influenza), sore throat (pharyngitis), back pain, and tingling or numbness in the skin (paresthesia).

The FDA can require a REMS to ensure that the benefits of a drug or biological product outweigh its risks. A REMS may consist of various elements, including:

- a medication guide to advise patients about important safety information for a drug;
- a communication plan to notify health care providers of serious risks associated with a particular drug; and
- elements to assure safe use, such as requirements that health care professionals who prescribe the drug, and pharmacies, practitioners or healthcare settings that dispense the drug, are specially certified.

Nplate is manufactured by Amgen, Inc. of Thousand Oaks, Calif.

Promacta is manufactured by Philadelphia-based GlaxoSmithKline.

For more information:

Nplate and Promacta Labeling and REMS Changes Drug Safety Communication

<http://www.fda.gov/Drugs/DrugSafety/ucm280165.htm>

Approved Risk Evaluation and Mitigation Strategies (REMS)

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>

Office of Hematology and Oncology Products

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm>

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