

Nplate[®]

romiplostim injection

NPLATE[®] PRODUCT FACT SHEET

INDICATIONS

Nplate[®] is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate[®] is indicated for the treatment of thrombocytopenia in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Nplate[®] is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. Nplate[®] should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate[®] should not be used in an attempt to normalize platelet counts.

PRODUCT INFORMATION

NDC 55513-221-01

Description 250 mcg/0.72 mL
single-use vial

Quantity One per carton



55513-222-01

500 mcg/1.2 mL
single-use vial

One per carton



55513-223-01

125 mcg/0.44 mL
single-use vial

One per carton



The prescribed Nplate[®] dose may consist of a very small volume (e.g., 0.15 mL). Administer Nplate[®] only with a syringe that contains 0.01 mL graduations.

STORAGE AND HANDLING REQUIREMENTS

Store Nplate[®] vials in their carton to protect from light until time of use. Keep Nplate[®] vials refrigerated at 2° to 8°C (36° to 46°F). Do not freeze.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.
www.amgen.com www.nplate.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Contact Amgen Assist360™: 1-888-4ASSIST (1-888-427-7478) or www.AmgenAssist360.com

Please see Important Safety Information on page 2.

IMPORTANT SAFETY INFORMATION

Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

- In Nplate[®] (romiplostim) clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate[®] is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than ITP.

Thrombotic/Thromboembolic Complications

- Thrombotic/thromboembolic complications may result from increases in platelet counts with Nplate[®] use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate[®].
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate[®] in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of $\geq 50 \times 10^9/L$.

Loss of Response to Nplate[®]

- Hyporesponsiveness or failure to maintain a platelet response with Nplate[®] should prompt a search for causative factors, including neutralizing antibodies to Nplate[®].
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate[®] and thrombopoietin (TPO).
- Discontinue Nplate[®] if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Adverse Reactions

Adult ITP

- In the placebo-controlled trials of adult ITP patients, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate[®] and 32% of patients receiving placebo. Adverse drug reactions in adults with a $\geq 5\%$ higher patient incidence in Nplate[®] versus placebo were Arthralgia (26%, 20%), Dizziness (17%, 0%), Insomnia (16%, 7%), Myalgia (14%, 2%), Pain in Extremity (13%, 5%), Abdominal Pain (11%, 0%), Shoulder Pain (8%, 0%), Dyspepsia (7%, 0%), and Paresthesia (6%, 0%).
- The safety profile of Nplate[®] was similar across patients, regardless of ITP duration. The following adverse reactions (at least 5% incidence and at least 5% more frequent with Nplate[®] compared with placebo or standard of care) occurred in Nplate[®] patients with ITP duration up to 12 months: bronchitis, sinusitis, vomiting, arthralgia, myalgia, headache, dizziness, diarrhea, upper respiratory tract infection, cough, nausea and oropharyngeal pain. The adverse reaction of thrombocytosis occurred with an incidence of 2% in adults with ITP duration up to 12 months.

Pediatric ITP

- The most common adverse reactions experienced by $\geq 5\%$ of patients receiving Nplate[®] with $\geq 5\%$ higher incidence in the Nplate[®] arm across the two placebo-controlled trials were contusion (41%), upper respiratory tract infection (31%), oropharyngeal pain (25%), pyrexia (24%), diarrhea (20%), rash (15%), and upper abdominal pain (14%).
- In pediatric patients of age ≥ 1 year receiving Nplate[®] for ITP, adverse reactions with an incidence of $\geq 25\%$ in the two randomized trials were: contusion (41%), upper respiratory tract infection (31%), and oropharyngeal pain (25%).
- In a long term, single arm, open label pediatric safety study, headache occurred in 78/203 patients (38%); the incidence rates of other adverse reactions were similar to those reported in the placebo controlled studies.

Nplate[®] administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. This formation may improve upon discontinuation of Nplate[®]. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate[®] therapy.

Please click here for full Prescribing Information and Medication Guide.

1. Nplate[®] (romiplostim) Prescribing Information and Medication Guide, Amgen.

