

# Nplate<sup>®</sup>

romiplostim injection

## NPLATE<sup>®</sup> PRODUCT FACT SHEET

### INDICATIONS

Nplate<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. Nplate<sup>®</sup> should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate<sup>®</sup> 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<sup>®</sup> dose may consist of a very small volume (e.g., 0.15 mL). Administer Nplate<sup>®</sup> only with a syringe that contains 0.01 mL graduations.

### STORAGE AND HANDLING REQUIREMENTS

Store Nplate<sup>®</sup> vials in their carton to protect from light until time of use. Keep Nplate<sup>®</sup> 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<sup>®</sup> (romiplostim) clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate<sup>®</sup> 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<sup>®</sup> use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate<sup>®</sup>.
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate<sup>®</sup> 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<sup>®</sup>

- Hyporesponsiveness or failure to maintain a platelet response with Nplate<sup>®</sup> should prompt a search for causative factors, including neutralizing antibodies to Nplate<sup>®</sup>.
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate<sup>®</sup> and thrombopoietin (TPO).
- Discontinue Nplate<sup>®</sup> 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<sup>®</sup> and 32% of patients receiving placebo. Adverse drug reactions in adults with a  $\geq 5\%$  higher patient incidence in Nplate<sup>®</sup> 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<sup>®</sup> was similar across patients, regardless of ITP duration. The following adverse reactions (at least 5% incidence and at least 5% more frequent with Nplate<sup>®</sup> compared with placebo or standard of care) occurred in Nplate<sup>®</sup> 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<sup>®</sup> with  $\geq 5\%$  higher incidence in the Nplate<sup>®</sup> 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  $\geq 1$  year receiving Nplate<sup>®</sup> 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%).

Nplate<sup>®</sup> 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<sup>®</sup>. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate<sup>®</sup> therapy.

***Please click here for full Prescribing Information and Medication Guide.***

1. Nplate<sup>®</sup> (romiplostim) Prescribing Information and Medication Guide, Amgen.

