

Nplate® (romiplostim) – Expanded indication

- On October 18, 2019, [Amgen announced](#) the [FDA approval](#) of [Nplate \(romiplostim\)](#), for the treatment of adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
 - Nplate was previously approved in adult patients with **chronic** ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
 - Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome or any cause of thrombocytopenia other than ITP.
 - Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding.
 - Nplate should not be used in an attempt to normalize platelet counts.
- Nplate is also approved 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.
- ITP is a rare, serious autoimmune disease characterized by low platelet counts in the blood and impaired platelet production. In the U.S., the estimated incidence of ITP is 6.1 per 100,000 adults annually. Nearly 20,000 people are newly diagnosed with ITP each year in the U.S.
- The approval of Nplate for the expanded indication was based on a single-arm, open-label study in 75 adult patients who had an insufficient response (platelet count $\leq 30 \times 10^9/L$) to first-line therapy. The median time from ITP diagnosis to study enrollment was 2.2 months (range 0.1 to 6.6); 60% of patients had ITP duration < 3 months.
 - Of the 75 patients enrolled, 70 (93%) had a platelet response $\geq 50 \times 10^9/L$ during the 12-month treatment period.
 - The mean number of months with platelet response during the 12-month treatment period was 9.2 (95% CI: 8.3, 10.1) months; the median was 11 (95% CI: 10, 11) months.
- The recommended initial dose of Nplate for all patients is 1 mcg/kg once weekly as a subcutaneous injection. The dose should be adjusted based on platelet response.
 - Refer to the Nplate drug label for additional dosing and administration recommendations.