2019 ITP clinical guidelines recommend limiting steroid use to ≤ 6 to 8 weeks before starting a second-line therapy, such as Nplate®[1,2]

In 2019 the American Society of Hematology (ASH) and the International Consensus Report (ICR) released updates to their guidelines for ITP.[1,2] These updates are based on a critical review of relevant articles published over the last 10 years.[1]

ASH recommendations[2]	ICR recommendation[1]
• **≤ 6 weeks of steroid treatment** is preferred vs prolonged, continuous use — Prolonged course defined as > 6 weeks, including treatment and taper • **Delay splenectomy** until after 1 year	• **6 weeks of steroid treatment** (8 weeks max) in patients who achieve a response* • **Defer splenectomy** until ≥ 1 year to 2 years

*Response defined as platelet count > 50 x 10^9/L.[1]

*Scan here or visit **Nplatehcp.com/guidelines** to access the full ASH and ICR Guidelines*

Nplate® is the only second-line ITP treatment approved for use within 6 months of diagnosis for adults with ITP[3,4]

Could your ITP patients benefit from moving to a second-line therapy earlier?

ITP, immune thrombocytopenia.

INDICATION

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 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.

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.

Please see accompanying full Prescribing Information and Medication Guide, and additional Important Safety Information throughout.

DON'T WAIT. Nplate® romiplostim injection

Right after insufficient response to steroids in adults with newly diagnosed/persistent ITP*

Start Nplate® earlier to give your patients platelet control and the opportunity for **TREATMENT-FREE REMISSION**[3,4,†]

Study design in newly diagnosed/persistent ITP (N = 75)[3-6]

Nplate® was studied in a 52-week, open-label, single-arm, phase 2 trial of adults with ITP for ≤ 6 months who had an insufficient response (platelet count ≤ 30 x 10^9/L) to first-line treatment, including corticosteroids.[‡] Nplate® was initiated at 1 mcg/kg and adjusted to achieve a platelet count ≥ 50 x 10^9/L to < 200 x 10^9/L.[§] At the end of the 52-week treatment period, patients who had not entered remission, were still receiving Nplate®, and had a platelet count ≥ 50 x 10^9/L had their dose tapered by 1 mcg every 2 weeks, as long as weekly platelet counts remained ≥ 50 x 10^9/L.

Primary endpoint:
Cumulative number of months in which a patient achieved a median platelet count ≥ 50 x 10^9/L

Select secondary endpoint:
Rate of remission, defined as maintaining every platelet count at ≥ 50 x 10^9/L for at least 6 months without any ITP treatment

The lack of a placebo control group prevents determination of remission rates without Nplate®.[4]

IMPORTANT SAFETY INFORMATION (cont'd)

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 ≥ 50 x 10^9/L.

Patients received Nplate® within 6 months of diagnosis, right after insufficient response to steroids[3,4]

Early use	Sustained response	Treatment-free remission
2.2 MONTHS	**61%**	**~1 out of 3†**
median time from diagnosis to initiation of Nplate®[3] (range, 0.1-6.6)	of patients sustained platelet counts ≥ 50 x 10^9/L for ≥ 11 months during the treatment period[4]	patients achieved treatment-free remission[3,4]

Could your next ITP patient benefit from earlier Nplate® use?

*Nplate was initiated following a platelet count ≤ 30 x 10^9/L at any time during the 4-week screening period. Nplate® was initiated within 6 months of ITP diagnosis.[3,4]
†Treatment-free remission was a secondary endpoint defined as maintaining every platelet count at ≥ 50 x 10^9/L for at least 6 months in the absence of any ITP treatment, and occurred in 32% of patients.[3,4]
‡First-line treatments could have also included immunoglobulins, anti-D immunoglobulin, or vinca alkaloids.[4]
§Adjustments were made following the recommended dosage regimen (Section 2.1 of the Nplate® Prescribing Information).

IMPORTANT SAFETY INFORMATION (cont'd)

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

- 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 ≥ 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.

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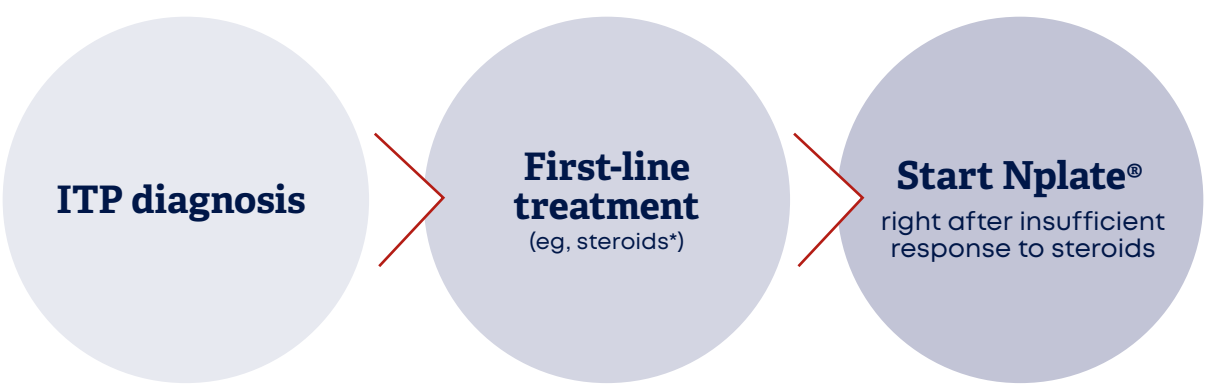
DON'T WAIT. Nplate® romiplostim injection

Nplate® is the only second-line ITP treatment approved for use within 6 months of diagnosis[3,4]

After more than a decade of clinical experience in chronic ITP, the indication for Nplate® was expanded to include newly diagnosed/persistent ITP, in adults who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.[3,4]

Potential treatment approach with Nplate®[3]



*Guidelines recommend a short course of steroids not to exceed 6 to 8 weeks.[1,2]

For early platelet control with the opportunity for treatment-free remission,
start Nplate® within 6 months of diagnosis[3]

REFERENCES: 1. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia.*Blood Adv.* 2019;3(22):3780-3817. **2.** Neunert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3838. **3.** Nplate® (romiplostim) prescribing information, Amgen. **4.** Newland A, Godeau VP, Priego V, et al. Remission and platelet responses with romiplostim in primary immune thrombocytopenia: final results from a phase 2 study. *Br J Haematol.* 2016;172(2):262-273. **5.** Newland A, Godeau B, Priego V, et al. Remission and platelet responses with romiplostim in primary immune thrombocytopenia: final results from a phase 2 study. *Br J Haematol.* 2016;172(Suppl):1-4. **6**. Data on file, Amgen; Clinical Study Report 20080435; 2014.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

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DON'T WAIT. Nplate® romiplostim injection