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Nplate

# **Nplate**

Pronunciation: N-plāt

Generic name: romiplostim [ ROM-i-PLOS-tim ]

Dosage form: injection(125 mcg, 250 mcg, 500 mcg)

Drug class: Platelet-stimulating agents

Medically reviewed by Melisa Puckey, BPharm. Last updated on Mar 31, 2025.

Uses Side effects Warnings Before taking Dosage Interactions FAQ

### What is Nplate?

Nplate (romiplostim) injection is a prescription medicine used to prevent serious bleeding episodes in people with chronic immune thrombocytopenic purpura (ITP), an autoimmune disorder with an increased risk of bruising or bleeding. Nplate is also used to treat patients who have been exposed to high levels of radiation (acute radiation syndrome) and have hematopoietic syndrome. Nplate works by stimulating the body to make more platelets increasing platelet production.

Nplate is a man-made form of a protein that mimics a natural hormone in your body called **thrombopoietin (TPO)** - a key regulator of platelet production. **Nplate mechanism of action is by binding to the TPO receptors on bone marrow cells which stimulates these cells to produce and release more platelets into the bloodstream**. Nplate is from a class of medicines called **thrombopoietin receptor agonists** 

Nplate is given as a weekly injection under the skin (subcutaneous injection) for immune thrombocytopenia and as a single dose for myelosuppressive radiation.

## Who can use Nplate?

Nplate is FDA-approved to treat:

#### Immune Thrombocytopenia (ITP) in:

- Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- 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.

### Hematopoietic Syndrome of Acute Radiation Syndrome in:

 Adults and pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation to increase survival. Nplate is **not** indicated for treating 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 increases the risk for bleeding.

Nplate should not be used in an attempt to normalize platelet counts

## What is immune thrombocytopenia?

Immune thrombocytopenia (ITP) is an autoimmune condition where the immune system mistakenly attacks and destroys platelets, leading to a low platelet count and a higher risk of bleeding. Platelets (also called thrombocytes) are small cell fragments responsible for blood clotting. Nplate helps increase platelet levels to lower the risk of bleeding.

### **Nplate side effects**

### **Common Nplate side effects**

Common Nplate side effects may include:

- Headache 35% (placebo 32%)
- Joint pain 26% (placebo 20%)
- Dizziness 17% (placebo 0%
- Muscle pain 14% (placebo 2%)
- Pain in your arms, legs, or shoulder 13% (placebo 5%)
- Abdominal pain 11% (placebo 0%)
- Shoulder pain 8%. (placebo 0%)
- Trouble sleeping 16% (placebo 7%)
- Indigestion 7% (placebo 0%)
- Numbness or tingling in your hands or feet 6% (placebo 0%)

**Headache was the most common side effect** occurring in 35% of patients receiving Nplate and 32% of patients receiving placebo. For the Nplate patients, 48% of headaches were mild, 31% were moderate, and 21% were severe.

These common side effects occurred in 5% or more of Nplate patients from placebo-controlled Studies 1 and 2.

### Serious Nplate side effects

Get emergency medical help if you have signs of an allergic reaction to Nplate: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Other serious side effects can occur, call your doctor at once if you have:

- · severe or ongoing diarrhea;
- purple or red spots under your skin;

- signs of an ear infection (more common in children) fever, ear pain or full feeling, trouble hearing, drainage from the ear, fussiness in a child;
- signs of a stroke sudden numbness or weakness (especially on one side of the body), severe headache, slurred speech, balance problems;
- signs of a blood clot in the lung chest pain, sudden cough, wheezing, rapid breathing, coughing up blood; or
- signs of a blood clot in your leg swelling, warmth, or redness in an arm or leg.

People who take Nplate may have an increased risk of developing new or worsening changes in the bone marrow called "increased reticulin". These changes may improve if you stop taking Nplate. Your healthcare provider may need to check your bone marrow for this problem during treatment with Nplate.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



Nplate side effects (more detail)

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# **Warnings**

Nplate is not a cure for ITP and it will not make your platelet counts normal if you have this condition.

Nplate may increase your risk of a blood clot or stroke. **Call your doctor right away if you have signs of a blood clot,** such as sudden numbness or weakness on one side of the body, chest pain, problems with speech or balance, warmth or swelling in an arm or leg.

Before you use Nplate, tell your doctor if you have kidney or liver disease.

Using Nplate long-term can cause harmful effects on your bone marrow that may result in serious blood cell disorders. To be sure this medication is helping your condition and not causing harmful effects, your blood will need to be tested often. Do not miss any scheduled visits to your doctor.

It may take up to 4 weeks of using this medicine before it is completely effective in preventing bleeding episodes. Talk with your doctor if you have any bruising or bleeding episodes after 4 weeks of treatment.

After you stop using Nplate, your risk of bleeding may be even higher than it was before you started treatment. Be extra careful to avoid cuts or injury for at least 2 weeks after you stop using Nplate. Your blood will need to be tested weekly during this time.

## Before taking this medicine

You should not use Nplate if you are allergic to romiplostim.

Using Nplate may increase your risk of developing blood cancers, especially if you have a myelodysplastic syndrome (bone marrow failure disorder, sometimes called "preleukemia"). Talk with your doctor if you have concerns about this risk.

To make sure Nplate is safe for you, tell your doctor if you have ever had:

- blood or bone marrow cancer such as leukemia, or myelodysplastic syndrome;
- bleeding problems or a blood clot;
- · surgery to remove your spleen; or
- · liver disease.

It is not known whether romiplostim will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

If you are pregnant, your name may be listed on a pregnancy registry to track the effects of romiplostim on the baby.

You should not breastfeed while using Nplate.

Nplate pregnancy and breastfeeding warnings (more detail)

## How is Nplate given?

Nplate is injected under the skin, usually once per week for Immune Thrombocytopenia (ITP) and as a single dose for Hematopoietic Syndrome of Acute Radiation Syndrome. A healthcare provider will give you this injection

It may take up to 4 weeks of before Nplate is completely effective in preventing bleeding episodes. Keep receiving the medication as directed. Talk with your doctor if you have any bruising or bleeding episodes after 4 weeks of treatment.

Using Nplate long-term can cause harmful effects on your bone marrow that may result in serious blood cell disorders. You will need frequent blood tests. Your treatment with this medicine may be delayed or permanently discontinued based on the results.

After you stop using Nplate, your risk of bleeding may be even higher than it was before you started treatment. Be extra careful to avoid cuts or injury for at least 2 weeks after you stop using Nplate. Your blood will need to be tested weekly

during this time.

1 Nplate patient tips (more detail)

## **Nplate dosing information**

### Usual Adult Nplate Dose for Idiopathic (Immune) Thrombocytopenic Purpura:

Initial dose: 1 mcg/kg subcutaneous injection once a week based on actual body weight; adjust the weekly dose by increments of 1 mcg/kg until the patients achieves a platelet count of 50 x 10(9)/L or greater

Maintenance dose: Use the lowest dose to achieve and maintain a platelet count of 50 x 10(9)/L or greater as needed to reduce bleeding risk.

Maximum dose: 10 mcg/kg/week

Duration of therapy: Discontinue this drug if platelets remain insufficient to avoid clinically important bleeding after 4 weeks at the maximum dose.

Comments: In clinical studies, most patients who responded to this drug achieved and maintained platelet counts of 50 x 10(9)/L or greater with a median dose of 2 mcg/kg..

### Usual Pediatric Nplate Dose for Idiopathic (Immune) Thrombocytopenic Purpura:

#### 1 Year or Older:

Initial dose: 1 mcg/kg subcutaneous injection once a week based on actual body weight; adjust the weekly dose by increments of 1 mcg/kg until the patients achieves a platelet count of 50 x 10(9)/L or greater

Maintenance dose: Use the lowest dose to achieve and maintain a platelet count of 50 x 10(9)/L or greater as needed to reduce bleeding risk.

Maximum dose: 10 mcg/kg/week

General information: Dose adjustments are based on changes in platelet counts and changes in body weight.

Reassessment of body weight is recommended every 12 weeks.

In a pediatric placebo-controlled clinical study, the median dose was 5.5 mcg/kg.

### Usual Adult Nplate Dose for Hematopoietic Syndrome of Acute Radiation Syndrome

For Adult and Pediatric Patients (including term neonates): The recommended dose of Nplate is 10 mcg/kg administered once as a subcutaneous injection. Administer the dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).

Detailed Nplate dosage information

## N-plate dosage forms and strengths

Single-dose vials.125 mcg, 250 mcg or 500 mcg of romiplostim as a lyophilized powder.

### What happens if I miss a dose?

Call your doctor for instructions if you miss an appointment for your Nplate injection.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

### What should I avoid while receiving Nplate?

Avoid activities that may increase your risk of bleeding or injury. Use extra care to prevent bleeding while shaving or brushing your teeth.

### What other drugs will affect Nplate?

Other drugs may interact with romiplostim, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

Not all possible drug interactions are listed here

1 Nplate drug interactions (more detail)

### Does Nplate interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Nplate	
+	
Enter a drug name	Add

## **Nplate Package Insert**

HCPs and patients often use the Nplate Package Insert (PI) for more detailed information about this medicine. The Nplate Package Insert contains more comprehensive information on Indications and Usage, Dosage and Administration, Clinical Pharmacology, Clinical Studies, Drug Interaction, and more. Discuss any medical questions you have with your HCP (health care professional). This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

The Package Insert is sometimes called Nplate Prescribing Information (PI) or FDA label.

## **Nplate J code**

#### Nplate J code is J2802 (New J code effective January 1, 2025)

J codes are used for medicines that are not taken orally and include injections, inhalations, and chemotherapies. J codes are important for accurate and consistent coding for billing and reimbursement purposes.

Your physician will need the Nplate J code when filling out forms for your treatment.

## Ingredients

Active ingredient: romiplostim

Inactive ingredients: L-histidine, mannitol, polysorbate 20, sucrose, and hydrochloric acid

### **Storage**

- Store in the refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
- · Do not freeze.
- If needed, unopened Nplate vials may be stored in the original carton at room temperature up to a maximum of 25°C (77°F) for a single period of up to 30 days. The new expiration date must be written in the space provided on the carton. Once stored at room temperature, do not place back in the refrigerator. If not used within the 30 days, discard Nplate.

### Company

Nplate Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799

### **Nplate Biosimilars**

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

### Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Nplate.

Nplate (romiplostim) - Amgen Inc.

Formulation type	Strength
Single-Dose Vial	125 mcg
Single-Dose Vial	250 mcg
Single-Dose Vial	500 mcg

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#### References

- 1. Romiplostim (Nplate), a Treatment Option for Immune (Idiopathic) Thrombocytopenic Purpura
- 2. Nplate Package Insert FDA

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### **Professional resources**

- Nplate prescribing information
- Romiplostim (AHFS Monograph)

### Related treatment guides

- Immune Thrombocytopenia
- Thrombocytopenia
- Hematopoietic Syndrome of Acute Radiation Syndrome

### **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

#### **Availability**

Rx Prescription only

### **Pregnancy & Lactation**

ം Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

### **Approval History**

10+ years FDA approved 2008

### **User Reviews & Ratings**

7.5 / 10

11 Reviews

### **Images**

Nplate 250 mcg lyophilized powder for injection





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