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2. Romiplostim

Romiplostim

Generic name: romiplostim

Brand name: [Nplate](#)

Dosage form: subcutaneous injection

Drug class: [Platelet-stimulating agents](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Jul 7, 2024.

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What is romiplostim?

Romiplostim (Nplate) stimulates thrombopoietin (TPO) production and may be used to treat low blood platelet counts (thrombocytopenia) in adults and children aged 1 year and older with immune thrombocytopenia (ITP) when certain medicines or surgery to remove the spleen have not worked well enough.

- When used in children, ITP must have been present for at least 6 months.

Romiplostim works by mimicking the action of natural TPO, which is a hormone produced by your liver and kidneys that regulates how many platelets you produce. Romiplostim's mechanism of action is to bind to and activate the same receptors that naturally occurring TPO uses to increase platelet production. This helps your body to make more platelets, which are cells that help your blood clot. Romiplostim is a TPO receptor agonist.

Romiplostim was FDA-approved on August 22, 2008, under the brand name Nplate. There is no generic Nplate available.

What is romiplostim used for?

Romiplostim is an injectable prescription medicine administered by a healthcare provider that may be used to treat low blood platelet counts ([thrombocytopenia](#)) in:

- adults with immune thrombocytopenia (ITP) when certain medicines or surgery to remove your spleen have not worked well enough
- children 1 year of age and older with ITP for at least 6 months when certain medicines or surgery to remove your spleen have not worked well enough.

Romiplostim may also be used to treat adults and children including newborns exposed to high levels of radiation (acute radiation syndrome). The effectiveness of romiplostim for this use was only studied in animals because it could not be studied in people.

What are the side effects of romiplostim?

The **most common side effects of romiplostim** in adults include:

- headache
- tingling or numbness in hands and feet
- joint pain
- bronchitis
- dizziness
- inflammation of the sinuses (sinusitis)
- trouble sleeping
- vomiting
- muscle tenderness or weakness
- pain in the arms and legs
- stomach (abdomen) pain
- shoulder pain
- indigestion
- diarrhea
- upper respiratory tract infection
- cough
- nausea
- pain in mouth and throat (oropharyngeal pain).

The **most common side effects of romiplostim** in children 1 year of age and older include:

- bruising
- upper respiratory tract infection
- pain in mouth and throat (oropharyngeal pain).

Serious side effects and warnings

Romiplostim can cause serious side effects, including:

Worsening of a precancerous blood condition to a blood cancer (leukemia). Romiplostim is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS), or for any condition other than immune thrombocytopenia (ITP). If you have MDS and receive romiplostim, your MDS condition may worsen and become acute leukemia. If MDS worsens to become acute leukemia you may die sooner from the acute leukemia.

Higher risk for blood clots. You may have a higher risk of getting a blood clot if your platelet count becomes high during treatment with romiplostim. You may have severe complications or die from some forms of blood clots, such as clots that spread to the lungs or that cause heart attacks or strokes.

- If you have a chronic liver disease, you may get blood clots in the veins of your liver. This may affect your liver function.

Injection of too much romiplostim may cause a **dangerous increase in your blood platelet count** and serious side effects. Your healthcare provider may change your dose or stop romiplostim depending upon the change in your blood platelet count. You must have blood platelet counts done before you start, during, and after romiplostim therapy is stopped (see “How should I receive romiplostim?” below).

People who take romiplostim 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 romiplostim. Your healthcare provider may need to check your bone marrow for this problem during treatment with romiplostim.

This is not a complete list of side effects. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Amgen at 1-800-77-AMGEN (1-800-772-6436).

 [Romiplostim side effects](#) (more detail)

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Before taking

Do not use romiplostim if you have a precancerous condition called myelodysplastic syndrome (MDS), or low platelet count caused by any condition other than ITP.

- Romiplostim is only used if your low platelet count and medical condition increase your risk of bleeding.
- Romiplostim is used to try to keep your platelet count at about 50,000 per microliter to lower the risk of bleeding. Romiplostim is not used to make your platelet count normal.

Before receiving romiplostim, tell your healthcare provider about all of your medical conditions, including if you:

- have had surgery to remove your spleen (splenectomy)
- have a bone marrow problem, including a blood cancer or MDS
- have or had a blood clot
- have chronic liver disease
- have bleeding problems
- are pregnant or intending to become pregnant
- are breastfeeding.

It is not known if romiplostim is safe and effective in children under the age of 1.

Pregnancy

Romiplostim may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with romiplostim.

Breastfeeding

Romiplostim may pass into your breast milk and harm your baby. Do not breastfeed during treatment with romiplostim.

 [Romiplostim pregnancy and breastfeeding warnings](#) (more detail)

How is romiplostim injection administered?

Romiplostim is administered by a healthcare provider as an injection under the skin (subcutaneous) once a week when used for ITP.

- When used to treat high levels of radiation, a healthcare provider will give it to you subcutaneously as a single injection.

During treatment for ITP, your healthcare provider will check your platelet count every week and change your dose of romiplostim as needed.

- This will continue until your healthcare provider decides that your dose of romiplostim can stay the same.
- After that, you will need to get blood tests every month.
- When you stop receiving romiplostim, you will need blood tests for at least 2 weeks to check if your platelet count drops too low.
- Tell your healthcare provider about any bruising or bleeding that occurs romiplostim treatment.

Romiplostim dosing

Recommended initial dose of romiplostim for adults and children with ITP

- Romiplostim 1 mcg/kg once weekly as a subcutaneous injection.
- Subsequent doses should be adjusted based on platelet response.

Recommended dose of romiplostim for adults and children acutely exposed to myelosuppressive doses of radiation

- Romiplostim 10 mcg/kg administered as a single subcutaneous injection.
- Administer the dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation.

i [Detailed Romiplostim dosage information](#)

What happens if I miss a dose?

If you miss a scheduled dose of romiplostim, call your healthcare provider to schedule your next dose as soon as possible.

What should I avoid while receiving romiplostim?

Avoid situations or medicines that may increase your risk of bleeding.

What other drugs will affect romiplostim?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products.

Romiplostim may be used with other medical ITP therapies, such as corticosteroids, danazol, azathioprine, intravenous immunoglobulin (IVIG), and anti-D immunoglobulin.

Know the medicines you take. Keep a list of them and show it to your healthcare provider or pharmacist when you get a new medicine.

i [Romiplostim drug interactions](#) (more detail)

Does romiplostim interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

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Storage

Store romiplostim vials 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.

Unopened romiplostim 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 30 days, discard romiplostim.

Romiplostim injection ingredients

Active ingredient: romiplostim.

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

Romiplostim is a peptibody, which is a peptide fused to an antibody. It was the first fully engineered peptibody designed to stimulate platelet production.

Who makes romiplostim?

Amgen Inc. makes romiplostim under the brand name Nplate.

- For the romiplostim package insert refer to the Nplate prescribing information and medication guide.

Romiplostim 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 romiplostim.

Nplate (romiplostim) - Amgen Inc.



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

View [Nplate](#) information in detail.

Popular FAQ

How long does Nplate (romiplostim) take to work?



How is Nplate (romiplostim) administered?



Is Nplate a chemotherapy drug?



What is Nplate used for and how does it work?



References

1. Keating GM. Romiplostim: a review of its use in immune thrombocytopenia. *Drugs*. 2012;72(3):415-435. doi:10.2165/11208260-000000000-00000
2. Bunin DI, Bakke J, Green CE, Javitz HS, Fielden M, Chang PY. Romiplostim (Nplate) as an effective radiation countermeasure to improve survival and platelet recovery in mice. *Int J Radiat Biol*. 2020;96(1):145-154. doi:10.1080/09553002.2019.1605465
3. [Nplate Prescribing Information and Medication Guide](#)

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DRUG STATUS

Availability

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 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

 Drug history at FDA



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