

## MEDICATION GUIDE

### Nplate™ (N-plät)

### (romiplostim)

Read this Medication Guide before you start Nplate and before each Nplate injection. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### What is the most important information I should know about Nplate?

Nplate can cause uncommon but serious side effects:

- **Bone marrow changes (increased reticulin and possible bone marrow fibrosis).** Long-term use of Nplate may cause changes in your bone marrow. These changes may lead to abnormal blood cells or your body making less blood cells. The mild form of these bone marrow changes is called “increased reticulin.” It is not known if this may progress to a more severe form called “fibrosis.” The mild form may cause no problems while the severe form may cause life-threatening blood problems. Signs of bone marrow changes may show up as abnormalities in your blood tests. Your healthcare provider will decide if abnormal blood tests mean that you should have bone marrow tests or if you should stop taking Nplate.
- **Worsening low blood platelet count (thrombocytopenia) and risk of bleeding shortly after stopping Nplate.** When you stop receiving Nplate, your low blood platelet count (thrombocytopenia) may become worse than before you started receiving Nplate. These effects are most likely to happen shortly after stopping Nplate and may last about 2 weeks. The lower platelet counts during this time period may increase your risk of bleeding, especially if you are taking a blood thinner or other medicine that affects platelets. Your healthcare provider will check your blood platelet counts for at least two weeks after you stop taking Nplate. Call your healthcare provider right away to report any bruising or bleeding.
- **High platelet counts and higher chance for blood clots.** You have a higher chance of getting a blood clot if your platelet count is too high during treatment with Nplate. 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. Your healthcare provider will check your blood platelet counts and change your dose or stop Nplate if your platelet counts get too high.
- **Worsening of blood cancers.** Nplate is not for use in patients with blood cancer or a precancerous condition called myelodysplastic syndrome (MDS). If you have one of these conditions, Nplate may worsen your cancer or condition and may cause you to die sooner.

When you are being treated with Nplate, your healthcare provider will closely monitor your Nplate dose and blood tests, including platelet counts.

- Nplate is available only after you and your healthcare provider agree to join a program that is intended to help in the safe use of Nplate. This program is called the “Nplate NEXUS Program.”
- Only a healthcare provider can inject a dose of Nplate. Injection of too much Nplate may cause a dangerous increase in your blood platelet count and serious side effects.
- During Nplate therapy, your healthcare provider may change your Nplate dose, depending upon the change in your blood platelet count. You must have blood platelet counts done before you start Nplate, during Nplate therapy, and after Nplate therapy is stopped.
- Nplate is used to try to keep your platelet count about 50,000 per microliter in order to lower the risk for bleeding. Nplate is not used to make your platelet count normal.

See “What are the possible side effects of Nplate?” for other side effects of Nplate.

### **What is Nplate?**

Nplate is a man-made protein medicine used to treat low blood platelet counts in adults with chronic immune (idiopathic) thrombocytopenic purpura (ITP), when other medicine to treat your ITP is not the best choice for you or surgery to remove the spleen has not worked well enough.

### **Nplate is only:**

- Prescribed by healthcare providers who are enrolled in the Nplate NEXUS Program.
- Given to patients who are enrolled in the Nplate NEXUS Program.
- Given by the enrolled healthcare provider or a provider under their direction. You may not give Nplate injections to yourself.

It is not known if Nplate works or if it is safe in people under the age of 18.

Nplate is for treatment of certain people with low blood platelet counts caused by chronic ITP, not low platelet counts caused by other conditions or diseases.

### **What should I tell my doctor before taking Nplate?**

#### **Tell your doctor about all 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 bleeding problems.
- Are pregnant, think you may be pregnant, or plan to get pregnant. It is not known if Nplate will harm an unborn baby.

***Pregnancy Registry:*** There is a registry for women who become pregnant during treatment with Nplate. If you become pregnant, consider this registry. The purpose of the registry is to collect safety information about the health of you and your baby. Contact the registry as soon as you become aware of the pregnancy, or ask your healthcare provider to contact the registry for you. You or your healthcare provider can get information and enroll in the registry by calling 1-877-Nplate1 (1-877-675-2831).

- Are breast-feeding or plan to breast-feed. It is not known if Nplate passes into your breast milk. You and your healthcare provider should decide whether you will take Nplate or breast-feed. You should not do both.

**Tell your healthcare provider about all the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal products. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

### **How should I take Nplate?**

To receive Nplate, you must first talk with your healthcare provider and understand the benefits and risks of Nplate. You must agree to and follow all of the instructions in the Nplate NEXUS Program.

Before you can begin to receive Nplate, your healthcare provider will:

- Explain the Nplate NEXUS Program to you.
- Answer all of your questions about Nplate and the Nplate NEXUS Program.
- Make sure you read the Nplate Medication Guide.
- Have you sign the Nplate NEXUS Patient Enrollment Form.

Nplate is given by your healthcare provider as a subcutaneous (SC) injection under the skin one time each week.

Your healthcare provider will check your platelet count every week and change your dose of Nplate as needed. This will continue until your healthcare provider decides that your dose of Nplate can stay the same. After that, you will need to have blood tests every month. When you stop receiving Nplate, 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 while you are receiving Nplate.

If you miss a scheduled dose of Nplate, call your healthcare provider to arrange for your next dose as soon as possible.

### **What should I avoid while receiving Nplate?**

Avoid situations that may increase your risk of bleeding, such as missing a scheduled dose of Nplate. You should arrange for your next dose as soon as possible. Call your doctor or the Nplate NEXUS Program at 1-877-Nplate1 (1-877-675-2831).

### **What are the possible side effects of Nplate?**

Nplate may cause serious side effects. See **“What is the most important information I should know about Nplate?”**

The most common side effects of Nplate are:

- Headache
- Joint pain
- Dizziness
- Trouble sleeping
- Muscle tenderness or weakness
- Pain in arms and legs
- Abdominal pain
- Shoulder pain
- Indigestion
- Tingling or numbness in hands and feet

These are not all the possible side effects of Nplate. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the Nplate NEXUS Program at 1-877-Nplate1 (1-877-675-2831) or FDA at 1-800-FDA-1088.

### **General information about the safe and effective use of Nplate.**

This Medication Guide summarizes the most important information about Nplate. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Nplate that is written for health professionals.

### **What are the ingredients in Nplate?**

Active ingredient: romiplostim

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

Nplate™ (romiplostim)

#### **Manufactured by:**

Amgen Inc.

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This product, its production, and/or its use may be covered by one or more U.S. Patents, including U.S. Patent Nos. 6,835,809 and 7,189,827, as well as other patents or patents pending.

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[www.Nplate.com](http://www.Nplate.com)

1-877-Nplate1 (1-877-675-2831)

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This Medication Guide has been approved by the U.S. Food and Drug Administration.