



Indication

Nplate[®] is a man-made protein medicine used to treat low blood platelet counts in adults with chronic immune thrombocytopenia (ITP), when certain other medicines, or surgery to remove your spleen, have not worked well enough.

Nplate[®] is not for use in people with a precancerous condition called myelodysplastic syndrome (MDS) or low platelet count caused by any condition other than chronic (lasting a long time) immune thrombocytopenia (ITP). Nplate[®] is only used if your low platelet count and medical condition increase your risk of bleeding. 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. It is not known if Nplate[®] works or if it is safe in people under the age of 18.

These questions may be helpful when discussing Nplate[®] and other chronic ITP treatments with your doctor. You may want to bring this to your next appointment.

Here are a few sample questions about ITP treatments you can ask your doctor

1. Based on my symptoms and medical history, what are my ITP treatment options? _____
2. How do these treatments work? _____
3. What are the risks and benefits of these treatments? _____
4. What side effects might these treatments have? _____
5. Are these short-term or long-term treatments? _____
6. What is the difference between long-term and short-term treatments? _____
7. Are these treatments FDA approved for chronic ITP? _____
8. How often will I need to get these treatments? _____
9. How long before I know if these treatments are working? _____
10. Will I still need to take other ITP medications? _____
11. Are there any medicines, foods, or beverages that are restricted while I'm on this treatment? _____
12. Do these treatments have patient support programs to help me with costs? _____

Questions about Nplate[®] (romiplostim)

1. How does Nplate[®] work differently from other ITP medications? _____
2. Is Nplate[®] right for me? _____
3. What are the most common side effects of Nplate[®]? _____
4. How long will it be before I know the treatment is working? _____
5. How frequently do I need to receive this treatment? _____
6. How long will I need to stay on this treatment? _____
7. Will my Nplate[®] dose change? _____
8. How often do I need to get my platelet counts checked after my dosing has stabilized my ITP? _____
9. Are there any symptoms or problems I might have during treatment that I should immediately tell my doctor about? _____

Important Safety Information

- Nplate[®] can cause serious side effects: worsening of a precancerous blood condition to a blood cancer (leukemia) in patients with MDS, higher risk for blood clots, and loss of response.
- In medical studies with Nplate[®], headache was the most common side effect.

http://pi.amgen.com/~media/amgen/repositories/pi-amgen-com/nplate/nplate_pi_hcp_english.ashx

Please see additional Important Safety Information on page 3. Please see [Prescribing Information and Medication Guide](#) for more information about Nplate[®].



Before starting Nplate®

Tell your healthcare provider 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 myelodysplastic syndrome (MDS).
- Have or had a blood clot.
- Have other bleeding disorders.
- Are receiving other treatments, such as acupuncture.
- Are pregnant, think you may be pregnant, or plan to become pregnant. It is not known if Nplate® will harm an unborn baby. A pregnancy registry has been established to collect information about the effects of Nplate® use during pregnancy. Physicians are encouraged to register pregnant patients, or pregnant women may enroll themselves in the Nplate® pregnancy registry by calling 1-800-77-AMGEN (1-800-772-6436).
- Are breastfeeding or plan to breastfeed. It is not known if Nplate® passes into your breast milk. You and your healthcare provider should decide whether you will take Nplate® or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, nutritional supplements, and herbal products. Know the medicines you take. Keep a list of them and show it to your doctor, nurse, and pharmacist when you get a new medicine.

List of Medications I Am Taking

(list all prescription medicines, over-the-counter medicines, nutritional supplements, and herbal products)

Brand Name	Generic Name	Taking for	Dosing Regimen

Notes

Important Safety Information

- Nplate® can cause serious side effects: worsening of a precancerous blood condition to a blood cancer (leukemia) in patients with MDS, higher risk for blood clots, and loss of response.
- In medical studies with Nplate®, headache was the most common side effect.

http://pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/nplate/nplate_pi_hcp_english.ashx

Please see additional Important Safety Information on page 3. Please see [Prescribing Information and Medication Guide](#) for more information about Nplate®.



Indication

Nplate® is a man-made protein medicine used to treat low blood platelet counts in adults with chronic immune thrombocytopenia (ITP), when certain other medicines, or surgery to remove your spleen, have not worked well enough.

Nplate® is not for use in people with a precancerous condition called myelodysplastic syndrome (MDS) or low platelet count caused by any condition other than chronic (lasting a long time) immune thrombocytopenia (ITP). Nplate® is only used if your low platelet count and medical condition increase your risk of bleeding. 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. It is not known if Nplate® works or if it is safe in people under the age of 18.

Important Safety Information

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

Nplate® can cause serious side effects:

- **Worsening of a precancerous blood condition to a blood cancer (leukemia):**

Nplate® is not for use in people with a precancerous condition called myelodysplastic syndromes (MDS) or for any condition other than chronic (lasting a long time) immune thrombocytopenia (ITP). If you have MDS and receive Nplate®, your MDS condition may worsen and become an 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 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 high.
- If you have a chronic liver disease, you may get blood clots in the veins of your liver. This may affect your liver function.

- **Loss of response:**

If you do not experience results from Nplate®, your immune system may have created a response that is counteractive to Nplate®. Your healthcare provider will monitor your platelet counts and test your blood regularly to determine if this is an issue.

- **Blood test monitoring:**

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.

- **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	- Stomach (Abdomen) pain	- Shoulder pain
- Indigestion	- Tingling or numbness in hands and feet		
- 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®.
- These are not all the possible side effects of Nplate®.
- If you have any questions about this information, be sure to discuss them with your doctor. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Pregnancy Surveillance Program: Women who become pregnant during Nplate treatment are encouraged to enroll in Amgen’s Pregnancy Surveillance Program. The purpose of this program is to collect safety information about the health of you and your baby. Contact the program as soon as you become aware of the pregnancy, or ask your healthcare provider to contact the program for you. You or your healthcare provider can get information and enroll in the program by calling 1-800-77-AMGEN (1-800-772-6436).

Please see [Prescribing Information and Medication Guide](#) for more information about Nplate®.

http://pi.amgen.com/~media/amgen/repositoriesites/pi-amgen-com/nplate/nplate_pi_hcp_english.ashx