

# Indication

Nplate<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> is only used if your low platelet count and medical condition increase your risk of bleeding. Nplate<sup>®</sup> is used to try to keep your platelet count about 50,000 per microliter in order to lower the risk for bleeding. Nplate<sup>®</sup> is not used to make your platelet count normal. It is not known if Nplate<sup>®</sup> works or if it is safe in people under the age of 18.

Keep track of important information by giving this tracker to your healthcare provider every time you receive your Nplate<sup>®</sup> treatment or get your platelet count checked.

Please fill in this information as you begin your Nplate® therapy.				
Name	Phone number			
Weight in kilograms (kg) at start of therapy	Date of platelet count and actual count at start of therapy			
Doctor's name	Doctor's phone number			

Date of Doctor Visit	Date of Blood Test	Platelet Count Per Microliter of Blood	Nplate® Dose (mcg/kg)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Your healthcare provider will check your platelet count (complete blood counts [CBCs] and blood smears) every week and adjust your dose of Nplate® as needed. This will continue until your platelet count has stabilized and your healthcare provider decides that your dose of Nplate® can stay the same. After that, you will need to have blood tests every month.

# **Important Safety Information**

- Nplate<sup>®</sup> 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.

Please see additional Important Safety Information on page 3. Please see <u>Prescribing Information and Medication</u> <u>Guide</u> for more information about Nplate<sup>®</sup>.

This platelet tracking sheet is for patient self-monitoring only. It is not intended to support medical diagnosis, clinical decision-making, or therapy.



# Nplate<sup>®</sup> Dose and Platelet Tracker



Date of Doctor Visit	Date of Blood Test	Platelet Count Per Microliter of Blood	Nplate <sup>®</sup> Dose (mcg/kg)
9.			
10.			
11.	$\bigcirc$ $\bigcirc$ $\bigcirc$		
2.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			
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28.			
29.			
30.			
31.			
32.			
33.			

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# **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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup>, your immune system may have created a response that is counteractive to Nplate<sup>®</sup>. 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<sup>®</sup> as needed. This will continue until your healthcare provider decides that your dose of Nplate<sup>®</sup> can stay the same. After that, you will need to have blood tests every month. When you stop receiving Nplate<sup>®</sup>, 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<sup>®</sup>?

- 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
   Muscle tenderness or weakness
   Indigestion
   Tingling or numbness in hands and feet
- People who take Nplate<sup>®</sup> 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<sup>®</sup>. Your healthcare provider may need to check your bone marrow for this problem during treatment with Nplate<sup>®</sup>.
- These are not all the possible side effects of Nplate<sup>®</sup>.
- 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®.