

# QUICK GUIDE TO HOME ADMINISTRATION OF NPLATE®

For **adult** patients who have chosen to give themselves Nplate® injections at home. The materials in this Home Administration Training pack will help ensure you can successfully inject Nplate® at home.

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

**AMGEN**®



# Materials in your Home Administration Training pack

ITEM	PURPOSE
<i>This Quick guide</i>	Gives you an overview of what is involved with home administration, including a description of the training process and ways to ensure you get the best result at home
<i>An Nplate® preparation mat</i>	Gives you a place on which to prepare your injection. Use in combination with your <i>Step-by-step guide</i> and <i>Self-administration diary</i>
<i>A Step-by-step guide to preparation and administration of the Nplate® injection</i>	An illustrated guide to self-administration, to help ensure you follow the steps correctly and in the right order
<i>A Self-administration DVD</i>	A step-by-step self-administration video
<i>A Self-administration diary</i>	A booklet so you can keep track of your schedule for training days, injection days, and clinic visits; also provides space for you to record your weekly dose and any problems you may experience with home preparation and administration

Please contact your healthcare professional with any questions or concerns you may have about ITP or Nplate®

## Table of contents

### NPLATE® FOR ITP (A BRIEF SUMMARY)

- Why platelet counts are lowered in ITP
- How Nplate® helps your body make more platelets

### TREATMENT WITH NPLATE®

- Taking the right dose at the right time
- Possible side effects
- Return of ITP symptoms?

### TRAINING FOR HOME ADMINISTRATION

### THE 4 STEPS OF HOME ADMINISTRATION TRAINING

### QUICK GUIDE CHECKLIST

Before training you will probably have questions for your healthcare professional around some of the issues listed below. All of these can be managed effectively through training. If you do have any remaining concerns, make sure you address these with your healthcare professional so that you feel confident and competent to prepare and administer the injection without their direct supervision. Also, make sure your healthcare professional completes the section titled 'Just in case you need support...' in your *Self-administration diary*.

Underdosing or overdosing

Incorrect storage of Nplate®

Contaminated work surface

Contamination of the Luer lock connector

Poor attachment of the syringe

Failure to prepare injection site

4

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8

# Nplate® for ITP (a brief summary)

## Why platelet counts are lowered in ITP

Adult ITP is a type of condition called an autoimmune disease. An autoimmune disease is when the body's defence (immune) system attacks a normal, healthy part of the body. For people with ITP, platelets are the healthy part of the body being attacked.

The immune system attack on platelets that occurs in ITP causes two things:

- The body destroys platelets much more quickly than usual, causing a low platelet count and lower levels of an important natural chemical that makes your body produce new platelets
- The body damages the special cells that create platelets, so each one makes fewer platelets than healthy cells would

## How Nplate® helps your body make more platelets

Nplate® treats ITP by increasing your platelet count, and thereby reducing your risk of bleeds. Nplate® raises platelet counts by mimicking the natural processes in the body responsible for making platelets.

Nplate® is a type of medicine known as a *TPO-receptor agonist (TPO-RA)*. TPO (thrombopoietin) is the natural chemical that your body produces to tell your bone marrow to make more platelets. TPO-RAs are treatments that act like your body's own TPO to increase the number of platelets that are produced.

# Treatment with Nplate®



## Taking the right dose at the right time

THE RIGHT DOSE	THE RIGHT TIME
<p>Because of the way Nplate® works, very small doses have a strong effect on your platelet count. Therefore, it's important that you get the right dose every time you're treated.</p> <p><b>Make sure that you administer the exact dose your doctor has prescribed.</b></p>	<p>It's important that you never skip a dose of Nplate®. If you have missed a dose, contact your doctor immediately for advice about when you should have your next dose.</p> <p>Also talk to your doctor first if you want to stop taking Nplate® for any reason. Nplate® should not be stopped without advice and guidance from a doctor.</p> <p>It is important to have a regular treatment schedule, even when you are travelling away from home.</p>

## Possible side effects

As with any medicine, Nplate® may be associated with side effects. Headache is very common, and may affect more than 1 in 10 people. You can find a full list in the package leaflet which accompanies every pack of Nplate®. If you do experience side effects let your healthcare professional know. Read your package leaflet for more information about possible side effects, and be sure you discuss any concerns with your doctor.

## Return of ITP symptoms?

If you experience any symptoms that you think may be a sign of a low platelet count, contact your doctor immediately. Your doctor may need to run some tests to see if there is a reason you are not responding so well to Nplate®. It is possible that your Nplate® dose may need to be changed. If this happens, you will not be able to administer Nplate® at home until your dose is stabilised.



# Training for home administration

Your doctor will give you the training you need to successfully prepare and inject Nplate® by yourself. This training involves 4 steps – as outlined on the following page.

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Remember to write your training schedule in your *Self-administration diary*

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Before you begin home administration, you should feel completely comfortable with preparing and administering your own weekly dose of Nplate®. Although the training involves 4 steps, the time required to learn how to prepare and administer Nplate® will vary across patients. The most important thing is that you feel confident and competent to prepare and administer the injection without the direct supervision of a healthcare professional.

# The 4 steps of home administration training



The training process involves the 4 steps described in the following table. After you've begun treating yourself with Nplate® at home, you'll need to attend the clinic once every 4 weeks for blood tests.

STEP 1	STEP 2	STEP 3
Your health professional shows you how to prepare and administer Nplate®	You prepare and administer Nplate® under the direct supervision of your health professional	You prepare and administer Nplate® at home
Your healthcare professional will use the <i>Nplate® preparation mat</i> and <i>Step-by-step guide</i> to demonstrate all the preparation and administration steps you will perform at home. You will receive your Nplate® dose at this time.  Your healthcare professional will complete the section titled "Just in case you need support..." in the your <i>Self-administration diary</i> , so you know who to contact in case of any questions.	Your healthcare professional will watch as you prepare and administer the correct dose of Nplate®. Before you begin home administration, they will make sure you can prepare and administer the right dose of Nplate® without additional assistance. You may perform this step more than once, until both you and your healthcare professional are confident in your ability to self-administer Nplate®.	You will prepare and self-administer Nplate® at home. Be sure to let your healthcare professional know if you had any problems, if you were able to administer the right dose, if you had any problems or have any concerns.  To make sure this step goes smoothly, write down the date and time you plan to administer your first at-home injection of Nplate®. Record the date and time in your <i>Self-administration diary</i> .

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**Step 4:** return for a blood test once every 4 weeks after you've begun home administration of Nplate®. At your first 4-weekly blood test, you will need to show your healthcare professional that you can prepare and self-administer Nplate® correctly.

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# Quick guide checklist



Each time you self-administer Nplate® please make sure that you follow this checklist.

✓	The right steps	Follow all the preparation and administration instructions in the <i>Step-by-step guide</i>
✓	The right materials	Use the <i>Nplate® preparation mat</i> to make sure you have all the materials you need, and check to make sure that the Nplate® vial is not expired
✓	Correct storage of Nplate®	Nplate® should be kept cool and out of direct light. Store your Nplate® in the refrigerator (but <i>not</i> the freezer) and in its original box. This medicine may be removed from the refrigerator for a maximum period of 30 days at room temperature (up to 25°C)
✓	The right dose of Nplate®	<p>Even in small doses Nplate® has an influence on platelet production, which is why you need to take the correct dose – so remember to check that you are administering the exact dose that your doctor has prescribed. Your doctor will tell you the correct dose to administer. This will be recorded in your <i>Self-administration diary</i></p> <p>If you inject too much or too little Nplate®, contact your doctor immediately. Use the information your healthcare professional wrote in your <i>Self-administration diary</i>, in the section titled “Just in case you need support...”</p>
✓	Cleanliness	<p><b>Clean hands:</b> wash your hands with soap and water and dry them thoroughly with a clean towel before you begin your preparation and administration of Nplate®</p> <p><b>Clean work surface:</b> clean your <i>Nplate® preparation mat</i> with an alcohol swab before placing the materials on it</p> <p><b>Clean tools:</b> All the preparation and injection materials in your Nplate® self-administration kit are clean and sterile. To ensure the materials remain sterile, remove them from the packaging only when instructed (as in the <i>Step-by-step guide</i>), and keep items in the air while preparing them</p> <p><b>Clean skin:</b> clean the injection site with a new alcohol swab immediately before you inject Nplate®</p>
✓	Firm connections	Make sure you follow the instructions and your training when attaching parts of the kit. For the connection between the vial and the syringe you may feel a small resistance when they twist together, however, when attaching the syringe tip (Luer lock) to the needle you will need to apply stronger force
✓	Disposal of needles and vials	After use, please dispose of the needles, syringes and vials safely in a sharps container