

SELECTING AND TRAINING PATIENTS FOR HOME ADMINISTRATION OF NPLATE®

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THE PATIENT HOME ADMINISTRATION TRAINING PACK INCLUDES A *SELF-ADMINISTRATION DIARY*, WITH SPACE FOR YOU TO RECORD THEIR CORRECT DOSE.

IN THE PATIENT'S *SELF-ADMINISTRATION DIARY*, MAKE SURE YOU WRITE AND DRAW THE PATIENT'S DOSE, CROSS OUT ANY OLD DOSES TO AVOID CONFUSION, AND COMPLETE THE SECTION TITLED, "JUST IN CASE YOU NEED SUPPORT..." ON THE BACK OF THE DIARY.

Home administration of Nplate® may be an option for some of your patients. This guide book will help you select and train appropriate patients to begin self-administration at home

- The checklist on the tear-off pad is designed to help ensure your patients take the right materials home
- The other patient-support items in this Home Administration Training pack will help support the training, confidence, and safety of patients administering Nplate® at home
 - See pages 10 and 11 for a complete list of the healthcare professional and patient support materials provided by Amgen as the Home Administration Training pack

SEE THE *PHYSICIAN EDUCATION* BOOKLET FOR ADDITIONAL INFORMATION ABOUT NPLATE®, INCLUDING DOSING AND TITRATION, SAFETY, CLINICAL EXPERIENCE, PATIENT POPULATIONS NOT STUDIED, AND AN OVERVIEW OF POSOLOGY AND RECONSTITUTION

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CRITERIA FOR SELECTING PATIENTS

IN ORDER TO SELF ADMINISTER NPLATE®
PATIENTS OR A CARER MUST BE:

Interested in home administration

A patient or carer must be competent and capable of self-administration, and not expected to require the presence or assistance of a healthcare professional for self administration. A patient can only be an appropriate candidate for Nplate® self-administration if they demonstrate:

- The ability to follow instructions
- The ability to properly handle all the required elements of self administration
- They have no physical condition that prevents them accurately reconstituting and injecting Nplate®



On a stable dose of Nplate®

For the purposes of self-administration, a stable dose of Nplate® means the patient's Nplate® dose has not required adjustment for at least 4 weeks (with platelet counts $\geq 50 \times 10^9/L$)

- Patients who need dose adjustments cannot return to self-administration until their dose has stabilised – that is, until their Nplate® dose has not required adjustment for at least 4 weeks



Willing to undergo a period of training

The patient or a carer have to undergo training in Nplate® preparation and self administration techniques. They have to commit to undergo this training and accept that they cannot self administer until they have demonstrated the ability to do so

TRAINING YOUR PATIENTS

It is recommended that patients who are eligible for home administration undergo a period of training conducted by you, and certain follow-up steps as outlined below.

STEP 1

Demonstration of reconstitution and administration technique (using the *Nplate® preparation mat* and the *Step-by-step guide*)

STEP 2

The patient is supervised while reconstituting and administering Nplate®. Only patients who demonstrate the ability to independently reconstitute and self-administer Nplate® are allowed to do so

STEP 3

Patient reconstitutes and self-administers Nplate® at home. Consider having a healthcare professional (e.g. nurse) call the patient after their first home injection to check for questions or problems

STEP 4

Monitoring of platelet count and full blood count on a 4-weekly basis (as per the Summary of Product Characteristics). After the first 4 weeks of self-administration, the patient should again be supervised while reconstituting and administering Nplate®. Only patients who demonstrate the ability to reconstitute and self-administer Nplate® should be allowed to continue doing so

Patient training should also include reminders that:

- Nplate® is a very potent drug, and dose precision is essential
- Nplate® must be stored in the original box (protected from light) and kept cool (in the refrigerator)
- Reconstitution and administration must be performed safely, on a clean surface and with clean hands, and the injection site should always be cleaned before the injection

PATIENTS CAN RECORD THEIR SUCCESS (AND ANY PROBLEMS) WITH SELF-ADMINISTRATION IN THEIR *SELF-ADMINISTRATION DIARY*. ENCOURAGE PATIENTS TO BRING THIS DIARY WITH THEM TO THEIR 4-WEEKLY MONITORING VISITS. IN THE PATIENT'S *SELF-ADMINISTRATION DIARY*, MAKE SURE YOU WRITE AND DRAW THE PATIENT'S DOSE, CROSS OUT ANY OLD DOSES TO AVOID CONFUSION, AND COMPLETE THE SECTION TITLED, "JUST IN CASE YOU NEED SUPPORT..." ON THE BACK OF THE DIARY.

PERFORMING TRAINING STEPS

It is recommended that the training process involves at least two one-on-one sessions between the trainer (the healthcare professional) and trainee (the patient and/or carer), as outlined here:

STEP 1

Demonstration of reconstitution and administration technique (including actual administration of the correct Nplate® dose)

The trainer will use the *Nplate® preparation mat* and the *Step-by-step guide* to demonstrate all the reconstitution and administration steps the patient will undertake at home. This stage of training will end with a healthcare professional administering an actual injection of the correct Nplate® dose.

STEP 2

The patient is supervised while reconstituting and administering Nplate®. Only patients who demonstrate the ability to reconstitute and self-administer Nplate® are allowed to do so

The trainer will observe the patient reconstituting and administering the correct dose of Nplate®, using the *Nplate® preparation mat* and the *Step-by-step guide*. Ideally, the patient will be able to reconstitute and administer the correct dose of Nplate® with minimal instruction from the trainer. At this stage, the patient must demonstrate their ability to inject the Nplate® dose safely and correctly.


STEP 3

Patient reconstitutes and self-administers Nplate® at home. Consider having a healthcare professional (e.g. nurse) call the patient after their first home injection to check for questions or problems

The trainee will prepare and self-administer the correct dose of Nplate® at their own home. The exact date and time of the injection should be agreed upon by the trainer and trainee, and written in the patient's *Self-administration diary*.

STEP 4

Remember to schedule 4-weekly monitoring visits with your self-administering patients. After the first 4 weeks of self-administration, the patient should



Some patients may be able to learn the steps in a 30-minute session. Others may require more time and/or may require a repetition of the first or second step.

This stage of training must include the following steps:

- Reminder to ensure dose certainty by referring to the dose card
- Demonstration of how to clean the *Nplate*® preparation mat and a reminder to wash hands
- Demonstration of how to lay the items out on the mat
- Demonstration of the reconstitution and administration steps
- Reminder to double-check the dose before administration
- Reminder to clean the injection site
- Instructions on how to administer a subcutaneous injection
- Reminder to dispose of all items properly

This stage of training is used to assess each patient's ability to successfully and correctly reconstitute and administer their *Nplate*® dose. If the patient requires significant assistance during the process, and/or the trainer feels the patient will not be able to perform the processes successfully at home (i.e. without assistance), then the patient should not be allowed to progress to home administration until the trainer feels the trainee is prepared.

This step needs to be repeated weekly until trainer and trainee are both confident that self-administration can be performed correctly.

If the trainee could not successfully reconstitute and administer the correct dose of *Nplate*®, the reason(s) for failure should be assessed and, if considered necessary, further training should be performed. The trainer should report the failure and the reason(s) for failure to Amgen.

again be supervised while reconstituting and administering *Nplate*®. Only patients who demonstrate the ability to reconstitute and self-administer *Nplate*® should be allowed to continue doing so.

IMPORTANT FACTORS TO KEEP IN MIND

The practicalities of home reconstitution and administration of Nplate® were assessed in a Human Factors Engineering study. The study identified the following issues, all of which can be managed by training:

Underdosing or overdosing

Incorrect storage of Nplate®

Contaminated work surface

Contamination of the Luer-lok connector

Poor attachment of the syringe

Failure to prepare injection site

During training, these issues should be verbally addressed and correct behaviour demonstrated (where appropriate).

PATIENT MONITORING:

DOSE ADJUSTMENTS AND HOME ADMINISTRATION

Patients' platelet counts must be monitored on a 4-weekly basis. Such monitoring will enable identification of patients who need dose adjustments. **Patients who need dose adjustments cannot return to self-administration until their dose has stabilised** – that is, until their Nplate® dose has not required adjustment for at least 4 weeks.

4-weekly monitoring visits may also be a good time to review the patients' *Self-administration diary*, in which they will have recorded their experiences of home administration. After the first 4 weeks of self-administration, the patient should again be supervised while reconstituting and administering Nplate®. Only patients who demonstrate the ability to reconstitute and self-administer Nplate® should be allowed to continue doing so.



THE IDENTIFIED RISKS OUTLINED HERE CAN ALL BE MANAGED BY THOROUGH TRAINING CONDUCTED AND SUPERVISED BY A HEALTHCARE PROFESSIONAL, AND THROUGH FOLLOW-UP MONITORING (POTENTIALLY BY PHONE).

PATIENT SUPPORT

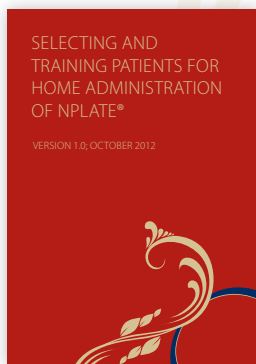
In addition to training and monitoring, patient support is integral to reducing the risks outlined on the previous page. Patient support may include:

The option to return to the clinic and perform reconstitution and self-administration again under the observation of a healthcare professional

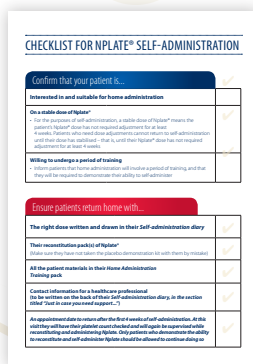
The option to have a dose administered at the clinic rather than at home

Distribution of additional copies of the materials from the Home Administration Training Pack

HOME ADMINISTRATION TRAINING PACK: HEALTHCARE PROFESSIONAL SUPPORT MATERIALS PROVIDED BY AMGEN



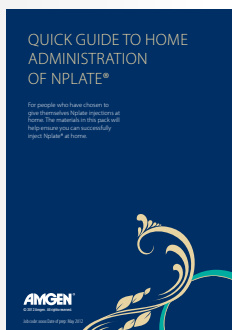
Selecting and training patients for home administration of Nplate® (this guide)



Checklist for Nplate® self-administration (a guide to selecting patients and ensuring they receive the right materials for home administration)

IN ADDITION TO THE HOME ADMINISTRATION TRAINING PACK SEE THE PHYSICIAN EDUCATION BOOKLET FOR ADDITIONAL INFORMATION ABOUT NPLATE®, INCLUDING DOSING AND TITRATION, SAFETY, CLINICAL EXPERIENCE, PATIENT POPULATIONS NOT STUDIED, AND AN OVERVIEW OF POSOLOGY AND RECONSTITUTION.

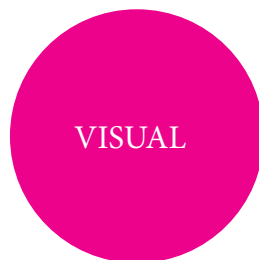
HOME ADMINISTRATION TRAINING PACK: PATIENT SUPPORT MATERIALS PROVIDED BY AMGEN



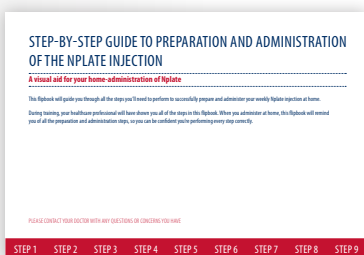
Quick guide booklet
(with a pre-administration checklist, an overview of Nplate®, an introduction to self-administration, and an overview of the training programme)



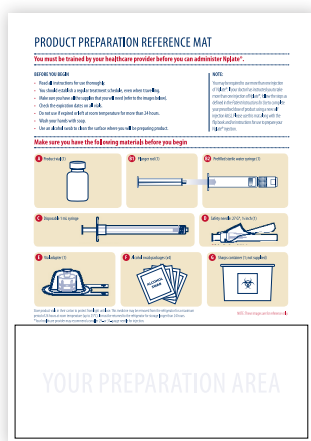
Self-administration diary
(including a page for recording both dose prescribed and dose administered)



Self-administration DVD



Step-by-step guide



Nplate® preparation mat

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