

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Nplate®

Romiplostim (rbe) ro"-mi"-p-lo"-sti"-m

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nplate.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nplate against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nplate is used for

Nplate is used to treat low blood platelet counts in people with immune (idiopathic) thrombocytopenic purpura (called ITP). ITP is a disease in which your immune system destroys your platelets.

Platelets are the cells in your blood that help seal cuts and form blood clots. If you have too few platelets you could bruise more easily than normal. You could also bleed for a long time after being injured. If your platelet count is very low, you may be at risk of serious, life-threatening bleeding.

This medicine works by increasing the number of platelets made by your body. Nplate makes your bone marrow produce more platelets. This helps to prevent bruising and bleeding.

Your doctor, however, may prescribe Nplate for another purpose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you are given Nplate

When you must not be given it

Do not use Nplate if you have an allergy to:

- any medicine containing romiplostim
- any of the ingredients listed at the end of this leaflet.
- any medicines that are produced using the bacteria *E.coli*.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- add any other specific reactions listed in the PI.

Do not use it after the expiry date (EXP) date printed on the pack.

If you use it after the expiry date has passed, it may have no effect, or an unexpected effect.

It may affect your developing baby if you take it during pregnancy.

Do not use it if the packaging is torn or shows signs of tampering.

Do not use it if the Nplate solution is cloudy or discoloured, or if it contains clumps or flakes.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you given it

Tell your doctor if:

- **you have allergies to:**
 - any other medicines
 - any other substances such as foods, preservatives or dyes.
- **you are pregnant or intend to become pregnant**
 - Nplate is not recommended to be used during pregnancy. Your doctor can discuss with you the risks and benefits involved.
 - you are breast-feeding or planning to breast-feed.
- **you have or have had any of the following medical conditions:**
 - liver problems
 - kidney problems
 - blood clot
 - cancer or precancer of the blood

If you have not told your doctor about any of the above, tell him/her before you start taking Nplate.

Tell your doctor if you stop taking Nplate. Your blood platelet count may return to low levels and put you at risk of bleeding if you stop taking Nplate. Your doctor will discuss the risks with you.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

How Nplate is given

Nplate is given as an injection under the skin. This is called a subcutaneous injection.

Nplate should be given to you under the guidance of an experienced doctor or nurse.

Self-administration is not recommended in children.

It is recommended that children receive their Nplate injection from an experienced doctor or nurse.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much is given

Adult

When you first start using Nplate your dose is 1 microgram per kilogram of your body weight, given once a week.

Your doctor will adjust your dose of Nplate depending on your blood platelet count.

Children (1 to 17 years)

When you first start using Nplate your dose is 1 microgram per kilogram of your body weight, given once a week.

Your doctor will adjust your dose of Nplate depending on your blood platelet count and any changes in your body weight.

When to use it

Nplate is injected once per week to keep your platelet counts in a safe range.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps control your condition, but does not cure it.

If you are given too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Nplate.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Telephone Amgen Medical Information Line on 1800 803 638 (free call within Australia) to enrol in Amgen's Pregnancy Surveillance Program if you become pregnant whilst using Nplate.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests to check your platelet levels from time to time to make sure the medicine is working.

Children (1 to 17 years)

Your doctor will regularly check your body weight to ensure your dose of Nplate is right for you.

Things you must not do

Do not use Nplate to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine without checking with your doctor.

If you stop taking it you may return to a low blood platelet count. You will be at risk of bruising and bleeding.

If you are taking medicines which prevent blood clots (anticoagulants or -anti-platelet therapy) when you lower the dose or stop taking Nplate, you will have a greater risk of bleeding.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nplate.

This medicine helps most people with low platelet counts, but may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by the lists of possible side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

Adults

- dizziness
- headache
- abdominal pain
- joint or muscle pain, including shoulder pain
- pain in your hands and feet
- trouble or difficulty in sleeping
- indigestion
- burning pain, redness and warmth in your hands and feet
- redness, heat or pain of skin
- allergic reaction.
- hive-like swelling beneath the skin

Children (1 to 17 years)

- upper respiratory tract infection including a cough, runny, or blocked nose
- inflammation or pain of the nose, throat or mouth
- upper abdominal pain
- gastroenteritis or diarrhoea
- fever
- itchy or non-itchy rash
- bruising
- inflammation of the eye (conjunctivitis)
- ear infection
- bleeding beneath the surface of the skin or bruising under the skin
- swelling in the limbs/hands/feet.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- tingling or numbness in your hands and feet.

If any of the following happens, stop using Nplate and tell your doctor immediately or seek medical attention:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects, for example,

Adults

- low blood platelet count after stopping Nplate,
- very high platelet count,
- increased bone marrow fibres

Children (1 to 17 years)

- very high platelet count

This can only be found when your doctor does tests from time to time to check your progress.

After using Nplate

Storage

If you need to store Nplate:

Keep your medicine in the refrigerator, between 2°C and 8°C. Do not freeze.

Keep your medicine in the pack until it is time to use it. Protect it from light.

If you take the powder out of the pack it will not keep well.

Do not shake or vigorously agitate the vial.

After Nplate powder has been dissolved, use the solution as soon as possible.

If the dissolved Nplate solution will not be used immediately, store it in the refrigerator, between 2°C and 8°C.

It can only be stored this way for up to 24 hours.

Use only one dose per vial of dissolved Nplate; do not re-enter the vial. Discard unused portions. Do not save unused Nplate for later administration.

Do not freeze dissolved Nplate solution.

Do not place Nplate or dissolved Nplate solution in a freezer or in the freezer compartment of a refrigerator.

Keep it where children cannot reach it.

Disposal

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

Your Nplate is supplied as white powder in a glass vial.

Nplate comes in two pack sizes:

- Nplate 250 µg/0.5 mL and
- Nplate 500 µg/1 mL

Each pack contains one vial.

It is prepared for use by dissolving the powder in sterile Water for Injections:

250µg/0.5mL vial containing 375µg romiplostim: powder dissolved in 0.72mL sterile Water for Injections

500µg/1mL vial containing 625µg romiplostim: powder dissolved in 1.2mL sterile Water for Injections.

The powder should dissolve in less than 2 minutes.

Ingredients

Active ingredient: romiplostim (rbe).

Inactive ingredients: mannitol, sucrose, histidine, diluted hydrochloric acid and polysorbate 20.

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Manufacturer/ Supplier

Nplate is supplied in Australia by:

Amgen Australia Pty Ltd
(ABN 31 051 057 428)
Level 7, 123 Epping Road
NORTH RYDE NSW 2113
Medical Information 1800 803 638

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375 µg vial: 147187

625 µg vial: 147188

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