

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Nplate?

Nplate contains the active ingredient romiplostim. Nplate is used to increase the number of platelets, and to prevent bruising and bleeding associated with a blood disorder called immune thrombocytopenia, commonly abbreviated as ITP.

For more information, see Section [1. Why am I using Nplate?](#) in the full CMI.

2. What should I know before I use Nplate?

Do not use if you have ever had an allergic reaction to romiplostim or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Nplate?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nplate and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Nplate?

Nplate is injected under the skin (subcutaneous).

More instructions can be found in Section [4. How do I use Nplate?](#) in the full CMI.

5. What should I know while using Nplate?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Nplate.• Keep all of your test appointments and doctor appointments so that your progress can be checked.• Tell your doctor immediately if you become pregnant while taking Nplate.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine unless your doctor tells you. If you stop taking Nplate, you are at risk of bleeding.
Driving or using machines	<ul style="list-style-type: none">• Nplate may cause temporary bouts of dizziness in some people and may impair your ability to safely drive or use machines.
Drinking alcohol	<ul style="list-style-type: none">• There is no information on the effects of using Nplate with alcohol.
Looking after your medicine	<ul style="list-style-type: none">• If you need to store a Nplate pack at home, keep it in the refrigerator, between 2°C and 8°C. Do not freeze it. Keep it out of sight and reach of children.

For more information, see Section [5. What should I know while using Nplate?](#) in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction, such as chest tightness, difficulty breathing, swelling of face lips and tongue, rash; and blood clots. Very common side effects include: headache; aches or pains in joints or muscles; dizziness; difficulty sleeping; pain; runny, or blocked nose; inflammation nasal or throat passages; cough; diarrhoea; rash; fever; bruising; infections.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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®

Active ingredient(s): romiplostim (ro-mip-lo-stim)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nplate. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nplate.**

Where to find information in this leaflet:

- [1. Why am I using Nplate?](#)
- [2. What should I know before I use Nplate?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Nplate?](#)
- [5. What should I know while using Nplate?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Nplate?

Nplate contains the active ingredient romiplostim.

Nplate works by stimulating the bone marrow to produce more platelets in patients with a bleeding disorder called ITP. Nplate is used to treat adults and children with ITP.

ITP is the short name for immune thrombocytopenia, a blood disorder where there are lower numbers of platelets than normal in your blood. ITP occurs when your body's immune system attacks and destroys platelets. If you have ITP, you may be at risk of serious, life-threatening bleeding.

Platelets are cells made in the bone marrow which help your blood to clot. Platelets circulate in your blood. If you have low platelets you could bruise more easily than normal or bleed for a long time after being injured.

Nplate should help to prevent bruising and bleeding associated with ITP. Nplate helps to control your condition but does not cure it.

2. What should I know before I use Nplate?

Warnings

Do not use Nplate if you are allergic to:

- romiplostim, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- other medicines that are produced by DNA technology using *Escherichia coli* (*E. coli*).

Check with your doctor if you:

- have surgery planned

- have any other medical conditions including:
 - liver problems
 - kidney problems
 - cancer or precancer of the blood
 - blood clots, or if blood clots are common in your family. The risk of blood clots may be increased if you:
 - are a female taking the contraceptive pill
 - take hormone replacement therapy
 - are a smoker
 - have recently had surgery or an injury
 - are overweight (obese)
 - are 65 years of age or older
 - are bedridden.
- take any medicines for any other condition. See Section 3. [What if I am taking other medicines?](#)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Use in children

Nplate is not recommended for use in children aged under 1 year.

Pregnancy

Check with your doctor if you are pregnant or intend to become pregnant. Nplate is not recommended to be used during pregnancy unless advised by your doctor. Your doctor can discuss the risks and benefits with you.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed. Nplate is not recommended for use if you are breast feeding. It is not known whether romiplostim is present in human milk. A decision on whether to discontinue breastfeeding or discontinue therapy with romiplostim should be made taking into account the benefit of breast-feeding to your child and the benefit of romiplostim therapy to you.

3. What if I am taking other medicines?

Some medicines may interfere with Nplate and affect how it works.

Tell your healthcare provider if you take:

- medicines used to prevent blood clots. There is a greater risk of bleeding when you lower the dose or stop taking Nplate. Your doctor will adjust your dose of Nplate to ensure that your platelet count does not become too high.

- any of the following medicines to treat your ITP, including, and not limited to:
 - medicines to reduce the activity of your immune system, such as:
 - azathioprine
 - corticosteroids
 - danazole (a synthetic hormone)
 - blood products called immunoglobulins, which are used to prevent some infections.

These may be reduced or stopped when given together with Nplate.

- any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nplate.

4. How do I use Nplate?

How to use Nplate

Nplate is given as an injection, under the skin. This is called a "sub-cutaneous" injection. It is given under the guidance of an experienced healthcare professional, by a carer, or can be self-administered by adults.

Self-administration is not recommended in children. It is advised that children receive their Nplate injection from an experienced doctor or nurse.

Follow the instructions provided and use Nplate until your doctor tells you to stop.

If injecting Nplate at home, use a syringe that has graduations in units of 0.01 mL, as the dose may be a very small volume.

When to use Nplate

Nplate should be taken every week to keep your platelet counts in a safe range.

How much to use

Your doctor will determine exactly how much Nplate you need. Dosing is usually between 1 to 10 micrograms per kilogram of body mass.

The dose is tailored to each patient and depends on body weight and platelet count.

The dose will be adjusted by your doctor to maintain long-term control of your platelet count.

Once your platelet count is under control, your doctor will continue to regularly check your blood.

Follow the instructions provided and use Nplate until your doctor tells you to stop.

If you forget to have Nplate

If you have missed a dose of Nplate, contact your doctor. Your doctor will discuss when you should have your next dose.

If you inject too much Nplate

If you think that you have used/been given too much Nplate, you may need urgent medical attention.

If you receive too much Nplate, you may not experience any physical symptoms. However, your platelet counts may rise to very high levels and this may increase the risk of blood clotting.

You should immediately:

- Phone the Poisons Information Centre (by calling 13 11 26), or
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Always take the outer carton of the medicine with you.

5. What should I know while using Nplate?

Things you should do

Continue using your medicine for as long as your doctor tells you. If you stop taking Nplate your platelet count will need to be monitored, and your doctor will discuss appropriate precautions with you.

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

Remind any doctor, dentist or pharmacist you visit that you are using Nplate.

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

Testing during your treatment

Your doctor will order regular blood tests to check your platelets levels and may adjust your Nplate dose.

If you experience a loss of response or failure to maintain a platelet response with Nplate, your doctor will investigate why. You may have increased bone marrow fibres (reticulin) or have developed antibodies which neutralise Nplate's activity.

Long-term use of Nplate may cause changes in your bone marrow. The changes may lead to abnormal blood cells or your body making less blood cells. The mild form of bone marrow changes is called "increased reticulin".

Signs of bone marrow changes may show up as unusual blood test results. Your doctor will decide if the results need further tests on your bone marrow or if you should stop taking Nplate.

Call your doctor straight away if you have:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing;
- generalised swelling
- wheezing
- rash, itching or hives on the skin or flushing.

You may be experiencing a severe allergic reaction and need urgent medical attention.

Things you should not do

- Do not stop using Nplate. Your doctor will decide if you should stop using Nplate. Your low blood platelet count is likely to recur and put you at risk of bleeding.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Nplate affects you.

Nplate may cause temporary bouts of dizziness in some people and may impair your ability to safely drive or use machines.

Looking after your medicine

If you need to store Nplate powder at home

- Keep the vials in the refrigerator, between 2°C and 8°C. Do not freeze.
- Store it in away from moisture and sunlight.
- Keep your medicine in the pack until it is time to use it. If you take the powder out of the pack it will not keep well.
- Keep it where young children cannot reach it.

Follow the instructions in the carton on how to take care of your medicine properly.

If you are injecting Nplate at home, after Nplate powder has been dissolved, use the solution as soon as possible.

- Do not shake or vigorously agitate the vial.
- Do not use Nplate if the solution is cloudy or discoloured, or if it contains clumps or flakes.
- Do not save unused Nplate for later administration.

If the dissolved Nplate solution cannot 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.**

- Do not freeze dissolved Nplate solution.

Getting rid of any unwanted medicine

Return any unused or expired Nplate to your pharmacist for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
<p>General: Tiredness; swelling of limbs, hands, or feet; fever; pain; toothache; unusual weakness.</p> <p>Nervous-system related: Headache; dizziness; "pins and needles" (numbness or a burning feeling that occurs most often in the hands, arms, legs, or feet, or elsewhere).</p> <p>Mood-related: Confusion; trouble sleeping; feeling nervous or anxious.</p> <p>Gut-related: Abdominal pain; constipation; nausea; diarrhoea; vomiting; indigestion or uncomfortable feeling in the stomach</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>or belching after eating; decreased appetite.</p> <p>Muscle-related: Cramps; muscle pain; aching muscles; muscle tenderness or weakness, not caused by exercise; Joint or muscle pain, including shoulder pain.</p> <p>Bone-related: Bone pain; back pain; pain in the extremities.</p> <p>Breathing-related: inflammation or pain of the nose, throat or mouth; cough; shortness of breath; difficulty in breathing; chest tightness; stuffy nose; blocked nose.</p> <p>Bleeding-related: Tiredness; headaches; being short of breath when exercising; dizziness and looking pale; bleeding or bruising more easily than normal; bleeding gums or in the mouth or nose; bleeding beneath the surface of the skin or bruising under the skin.</p>	

Less serious side effects

Less serious side effects	What to do
<p>Infection-related: A common cold; infections of the mouth, nose, throat, voice box and windpipe, or ears; the flu; inflammation of the sinuses; inflammation of the passages that carry air to the lungs; inflammation of the eye (conjunctivitis).</p> <p>Immune system-related: Allergic reactions.</p> <p>Skin-related: Red or purple, flat, pinhead spots under the skin; rash; itching; skin abrasion; cuts; bruising; hive-like swelling beneath the skin; redness, heat or pain of skin.</p> <p>Blood vessel-related: Bruising; blood clots; bleeding; burning pain/redness in the feet, hands, arms, legs, ears and face; high blood pressure.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Serious allergy-related: Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.</p> <p>Immune system-related:</p>	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
Shortness of breath, flushing, itching, swelling of face and generalized swelling. Blood and lymphatic system related: Bone marrow problems (detected in tests); blood clots.	notice any of these serious side effects.

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Nplate contains

Active ingredient (main ingredient)	romiplostim
Other ingredients (inactive ingredients)	histidine polysorbate 20 (E432) diluted hydrochloric acid (E507)
Potential allergens	mannitol (E421) sucrose

Do not take this medicine if you are allergic to any of these ingredients.

What Nplate looks like

Nplate is a white powder for solution for subcutaneous injection is supplied in a 5 mL single-dose, clear, glass vial with stopper, aluminium seal, and flip-off cap.

Nplate cartons contain one vial.

Reconstitution and/or dilution yields a clear, colourless, solution. The solution in each vial includes an excess to enable the prescribed dose to be removed.

Nplate 250 micrograms/0.5 mL powder for injection (AUST R 147187).

Nplate 500 micrograms/1 mL powder for injection (AUST R 147188).

Who distributes Nplate?

Amgen Australia Pty Ltd,
Level 11, 10 Carrington Street,
Sydney NSW 2000.
Ph: 1800 803 638