



# Treatment with Nplate<sup>®</sup> (romiplostim) for immune thrombocytopenia (ITP)

## A patient's guide

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**AMGEN**<sup>®</sup>

Oncology

# + Important contacts

Please fill this in as you may find it useful for future reference.

Nurse's name .....

Telephone number .....

Bleep number .....

Consultant's name.....

Telephone number .....

Out-of-hours (emergency) number .....

Other useful contact information.....

# + Contents

<b>Introduction</b> .....	<b>7</b>
<b>ITP</b> .....	<b>5</b>
What is ITP? .....	6
What are platelets?.....	6
What happens in ITP? .....	7
Treatment of ITP .....	9
<b>Introduction to romiplostim</b> .....	<b>11</b>
About romiplostim.....	12
Why have I been prescribed romiplostim? .....	13
Administration and dosing .....	13
Important information before starting romiplostim.....	15
Important information while receiving romiplostim.....	15
Important information before stopping romiplostim.....	16
Treatment aims.....	17
Side effects.....	18
<b>Looking after yourself</b> .....	<b>19</b>
What can I do for my general well-being? .....	20
<b>Information and support</b> .....	<b>22</b>
What support is available?.....	23
<b>Useful terms</b> .....	<b>24</b>
<b>Notes</b> .....	<b>27</b>
<b>References</b> .....	<b>28</b>

# + Introduction

This patient guide has been given to you because you have been prescribed Nplate<sup>®</sup>, also known as romiplostim, for the treatment of chronic ITP.

Please read the patient information leaflet (PIL) that comes with romiplostim carefully before you start using this medicine because it contains important information for you. Please keep the leaflet in a safe place as you may need to refer to it quickly.

It is also recommended that you read the patient information leaflets of all the medicines that you take with romiplostim.

If you have any questions or concerns about any aspect of your treatment, please speak to your doctor, nurse or pharmacist, who will be able to advise you.

Throughout this patient guide, any words in ***bold italic*** text on first use have a more detailed explanation in the **Useful terms** section.



+ ITP

A detailed microscopic view of blood cells. The background is dark, with numerous red blood cells (erythrocytes) appearing as bright red, biconcave discs. A prominent white blood cell (leukocyte) is visible in the center, characterized by a large, multi-lobed nucleus and a granular cytoplasm. Other smaller white blood cells and platelets are scattered throughout the field.

# + What is ITP?

## ITP is an autoimmune disease that affects one component of the blood

**ITP**, also known as immune (*idiopathic*) thrombocytopenic purpura, is a type of condition called an **autoimmune disease**. An autoimmune disease occurs when the **immune system** attacks a normal, healthy part of the body. For people with ITP, the healthy part of the body being attacked is an important component of the blood called **platelets**. The cause of this immune reaction is often unknown.

## What are platelets?

Platelets are small, irregularly shaped cells found in the blood. They are formed by specialised cells in the **bone marrow** in response to an important natural chemical that makes your body produce new platelets, **thrombopoietin (TPO)** (Figure 1). The platelets' main job is to seal cuts by forming **blood clots**.

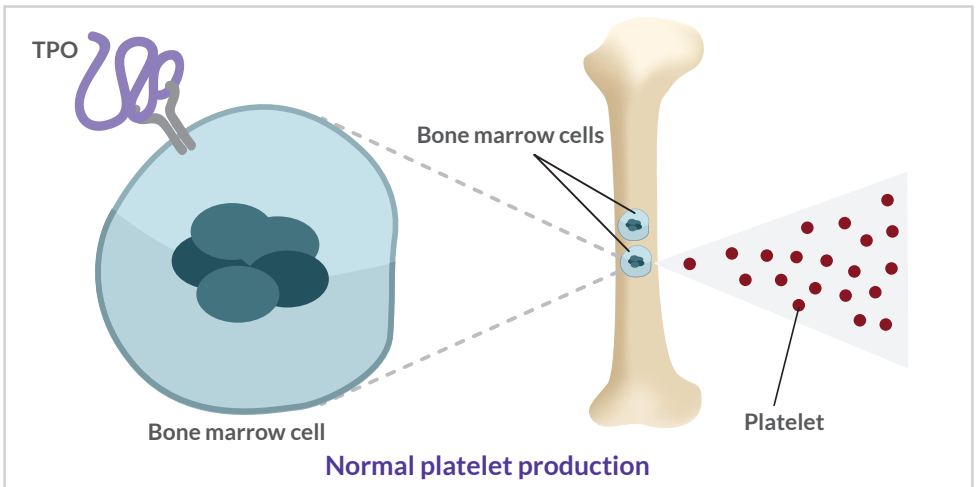


Figure 1: Platelets are made in the bone marrow in response to TPO.



## What happens in ITP?

**Antibodies** are an important component of the immune system, helping the body to fight infection. However, in ITP antibodies attack platelets and also the cells that produce platelets, which results in two simultaneous effects, as shown in Figure 2.

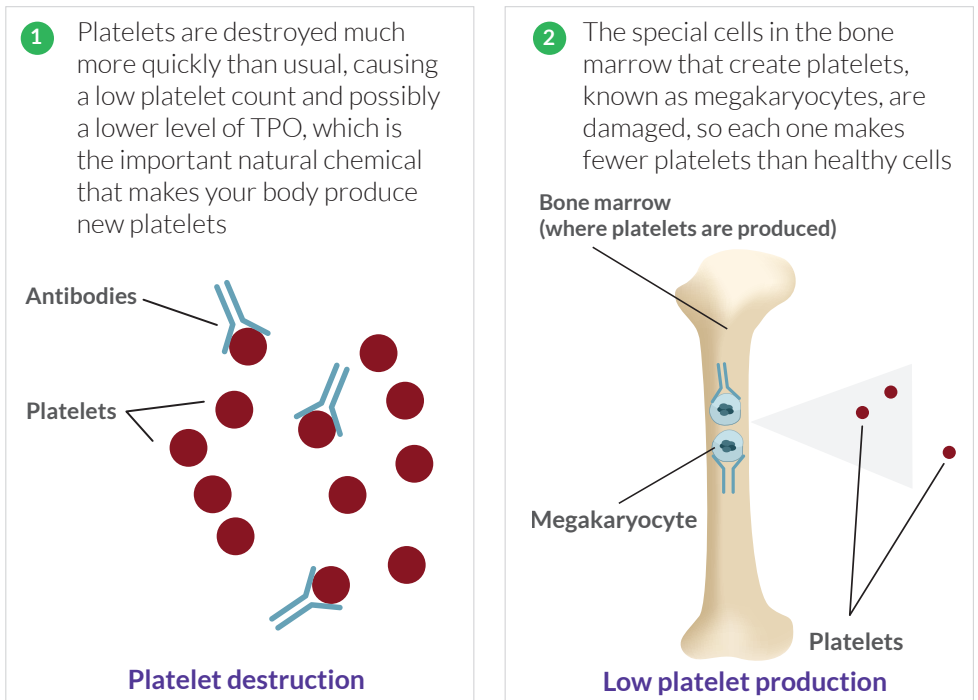


Figure 2: In ITP, antibodies cause platelets to be destroyed (1) and also result in insufficient new platelets being made in the bone marrow (2).

If you do not have enough platelets, your blood may not clot as quickly as it needs to. As a result, you may be prone to bruising on various parts of your body. You may also bleed without warning, and if your platelet count is low you may discover blood in your urine or stools.

The signs and symptoms experienced with ITP will vary from person to person. Table 1 lists some common signs and symptoms associated with ITP.



Table 1: Commonly experienced signs and symptoms with ITP

Symptom	Pronounced	Description
Epistaxis	ep-is-TAX-is	A nose bleed
Haematoma	hee-mah-TO-ma	A collection of clotted or partially clotted blood under the skin; looks or feels like a lump
Menorrhagia	men-or-HAGE-i-a	Very heavy menstrual bleeding
Mucosal bleeding	myu-KO-sal	Bleeding that occurs within the mucous membranes (skin that lines body passages and cavities, such as the mouth)
Petechiae	peh-TEE-kee-ay	Tiny red or purple dots on the skin; petechiae can look like a rash
Purpura	PURR-pure-ah	Patches of purple discolouration due to bleeding under the skin



## Treatment of ITP

Although there is currently no known cure for ITP, there are a number of treatments which can help keep ITP under control.

The choice of treatment depends on a number of factors including your symptoms and other conditions you may have, as well as your lifestyle and personal preferences. The type of treatment may also depend on the stage of disease (see Table 2) as well as the treatments you have already had and how you responded to them.



Table 2: ITP is classed into disease phases

ITP phase	Definition
Newly diagnosed	Within 3 months of diagnosis
Persistent	Between 3 to 12 months from diagnosis
Chronic	Longer than 12 months from diagnosis

There are several different classes of medicine or approaches which are used to treat ITP. They work by increasing the number of platelets in the blood in one of two ways:

- Stopping the body's immune system from destroying platelets
- Prompting the body's own natural processes to make new platelets

Some of these medicines or approaches are only to be used at specific disease phases or following certain other treatments, for example romiplostim is used for chronic disease that has not responded or has stopped responding (is **refractory**) to other treatments. Classes of medicines for the treatment of ITP are listed in Table 3.



Table 3: Classes of medicines/approaches for the treatment of ITP

Medicine/approach	How this works
<b><i>Corticosteroids</i></b>	There are a variety of medicines which reduce the activity of the body's immune system. In ITP, these medicines may help your platelet count improve by stopping the body's immune system from destroying platelets
<b><i>Immunoglobulins</i></b>	
<b><i>Immunosuppressants</i></b>	
<b><i>Monoclonal antibodies</i></b>	
<b><i>Splenectomy</i></b>	This surgical approach to remove the <b>spleen</b> removes the main site of platelet destruction in ITP
<b><i>Thrombopoietin-receptor agonists (TPO-RAs) eg romiplostim</i></b>	This type of medicine acts like your body's natural processes (via the action of thrombopoietin [TPO]) to increase the number of platelets that are produced

# + Introduction to romiplostim



# + About romiplostim

## Romiplostim helps your body make more platelets

Romiplostim is a type of medicine known as a **thrombopoietin-receptor agonist (TPO-RA)**. Thrombopoietin (TPO) 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 as shown in Figure 3.

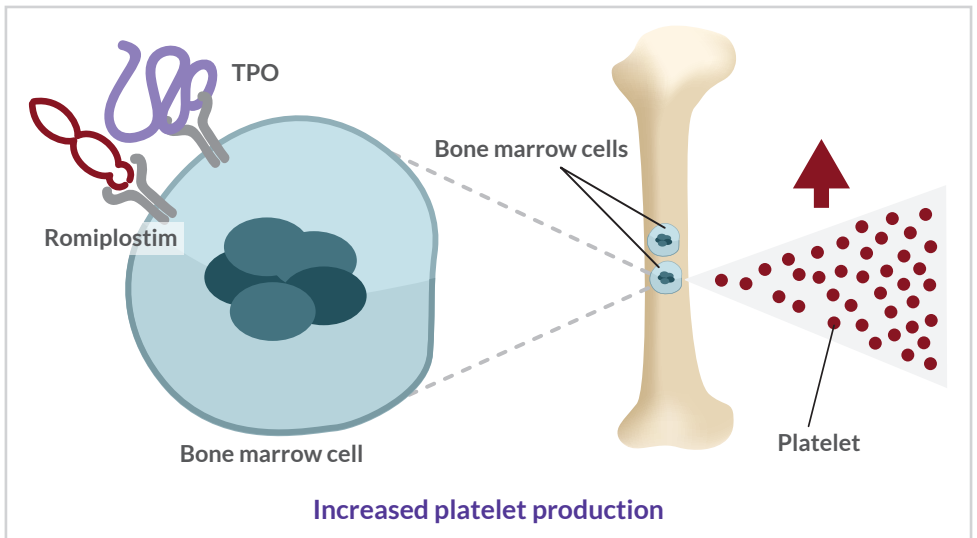


Figure 3: In ITP, romiplostim acts like TPO to increase the number of platelets produced.

## Why have I been prescribed romiplostim?

Romiplostim is used to treat chronic ITP in patients who may or may not have had their spleen removed.

Your doctor has decided that romiplostim is the most appropriate treatment because your disease has not responded or stopped responding to other treatments such as corticosteroids and immunoglobulins.

The overall aim of treatment is to increase your platelet count to prevent complications of ITP.

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## Administration and dosing

### How will I be given romiplostim?

Romiplostim will be given under the direct supervision of your doctor, who will closely control the amount of romiplostim given to you.

Romiplostim is given as an injection under your skin. Your doctor will check your platelet count on a regular basis and adjust your dose of romiplostim as needed.

Once your platelet count is under control, your doctor will continue to regularly check your blood. Your dose may be adjusted further in order to maintain long-term control of your platelet count.

See Table 4 for more questions and answers.



Table 4: Administration and dosing questions

<p><b>Can I self-administer romiplostim?</b></p>	<p>After suitable training, there is a possibility that your doctor may also allow you to inject romiplostim yourself. Please speak to your doctor or nurse for more information about this.</p> <p>Always use romiplostim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure of how to use romiplostim.</p> <p>If your doctor has allowed you to self-inject romiplostim, you should follow-up with your doctor every month to have the doctor determine if romiplostim is working for you or if another treatment needs to be considered.</p> <p>After the first month of self-injecting romiplostim, you will need to show that you can still prepare and inject romiplostim correctly.</p>
<p><b>What should I do if I receive more or less romiplostim than I should?</b></p>	<p>Your doctor will ensure that you receive the right amount of romiplostim. If you have been given more or less romiplostim than you should, you may not experience any physical symptoms but your blood platelet counts may change to very high or low levels, and this may increase the risk of <b>blood clotting</b> or increase the risk of bleeding, respectively. Therefore, if your doctor suspects that you have been given more or less romiplostim than you should, it is recommended that you are monitored for any signs or symptoms of side effects and that you are given appropriate treatment immediately.</p> <p>If your doctor has allowed you to self-inject and you use more or less romiplostim than you should, then inform your doctor immediately.</p>
<p><b>What should I do if I miss a dose of romiplostim?</b></p>	<p>You should never skip a dose of romiplostim. If you have missed a dose, talk to your doctor about when you should have your next dose.</p> <p>If your doctor has allowed you to self-inject and you forget to inject romiplostim, then inform your doctor immediately.</p>
<p><b>Can I stop using romiplostim?</b></p>	<p>Talk to your doctor first if you want to stop taking romiplostim for any reason.</p> <p>If you stop taking romiplostim, a low blood platelet count (<b>thrombocytopenia</b>) is likely to reoccur. Your platelet count will have to be monitored and your doctor will discuss appropriate precautions with you.</p>

## Important information before starting romiplostim

Discuss with your doctor:

- If you or a member of your family have ever had a blood clot
- If you are pregnant or breastfeeding  
Romiplostim is not recommended during pregnancy or when breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please discuss this with your doctor or nurse.
- If you are receiving any other medicines  
Some medicines and supplements can interact with your ITP by affecting platelets. Tell your doctor about all medicines you are taking, have recently taken or might take, including painkillers, vitamins, supplements and herbal remedies, and explain why you take them.

Please ensure that you read the patient information leaflet (PIL) before starting treatment with romiplostim.

## Important information while receiving romiplostim

- Driving  
Some patients on romiplostim have experienced dizziness. Although this dizziness only lasted a short period of time, be aware that it could affect your ability to drive. You should speak with your doctor before driving or using machines.



## ● Tooth care and visiting the dentist

Even people without ITP sometimes experience gum bleeds when they brush their teeth. Gum bleeds can be more of a concern when you have ITP. Therefore:

- Always use a soft toothbrush

Remember that good dental hygiene is important for your health.

Everyone's gums are prone to bleeding during a visit to the dentist. Because your gums may be especially prone to bleeding, you must tell your dentist that you have ITP, so he or she can be as careful as possible.

The ITP Support Association has created a guide for dentists treating patients with ITP. Please see the section on **Information and support** for their contact details.

## ● Travelling with romiplostim

You can travel while you are receiving romiplostim. Romiplostim may be removed from the refrigerator for a period of 30 days and kept at room temperature (up to 25°C) when stored in the original carton.

If you are planning to travel abroad, talk to your doctor before you go and also consult with your airline provider to ensure you are aware of all their requirements.

## Important information before stopping romiplostim

Your doctor will decide if you should stop taking romiplostim. If you want to stop for any reason, discuss the reasons with your doctor. Be aware that if you stop taking romiplostim, a low platelet count (thrombocytopenia) may reoccur. Should you stop romiplostim for any reason, you will need to have your platelet count monitored and your doctor will need to talk to you about taking appropriate precautions. It is therefore necessary that you speak to your doctor before stopping treatment.

## Treatment aims

### How do I know romiplostim is working?

ITP treatment must be individualised to suit your particular needs. The goal of treatment is to minimise your bleeding risk as much as possible by increasing your platelet count.

In general, the goal of romiplostim treatment is to keep your platelet count high enough to reduce the risk of bleeding events.

Your doctor will investigate whether your ITP is under control from results of regular blood tests. You may also notice an improvement in your symptoms.

Signs that treatment is working include (but are not restricted to):

- Improved blood test results, for example an increase in the platelet count
- Improvement in your symptoms, which may include:
  - Reduced bruising
  - Reduced bleeding

Your doctor and/or nurse will carry out regular tests and check on your general well-being. You may be asked how you are feeling and if you are experiencing improvement in your symptoms. It is important to discuss any treatment side effects you may be experiencing, have experienced or are worried about.

## Side effects

### Reporting of side effects

If you have any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Side effects can also be reported to Amgen Limited on 01223 436441.

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

### Side effects

As with any medicine, romiplostim may be associated with side effects. The most common side effects are:

- Headache
- Allergic reactions
- Upper respiratory tract infections

Please read the patient information leaflet (PIL) that comes with your medicine for more information about possible side effects, and be sure you discuss any concerns with your doctor.

Always read the patient information leaflet (PIL) that comes with your medicine. This leaflet contains a complete list of side effects and their frequency.

If you have any questions about side effects, or any other aspect of your treatment, please speak to your doctor or nurse.

# + Looking after yourself



# + What can I do for my general well-being?

**There are a few simple things that you can do each day to help look after yourself both physically and emotionally**

## Medicines and supplements

Some medicines and supplements can interact with your ITP by affecting platelets. Tell your doctor about all medicines you are taking, have recently taken or might take, including painkillers, vitamins, supplements and herbal remedies, and explain why you take them.

## Pick your painkillers

Talk to your doctor before taking any painkillers or other medicines. In particular, non-steroidal anti-inflammatories (NSAIDs) like aspirin and ibuprofen may cause low platelet counts. Ask your doctor to recommend a painkiller for you.

## General wellness

Your ability to fight infection can be reduced by some of the treatments for ITP. This may mean that you can develop infections more easily, such as repeated colds, flu and coughs, and chest and other infections. You can minimise the risk by avoiding situations where you may be exposed to infection, such as crowded places, day nurseries and schools, as much as you can.

Where possible, avoid close contact with people who currently have infections that can be easily transmitted, including chickenpox, shingles and measles. Also ensure that you wash your hands regularly with hot soapy water, especially after going to the toilet and before eating. Using an antibacterial hand gel can also help after touching shared surfaces and using public transport.

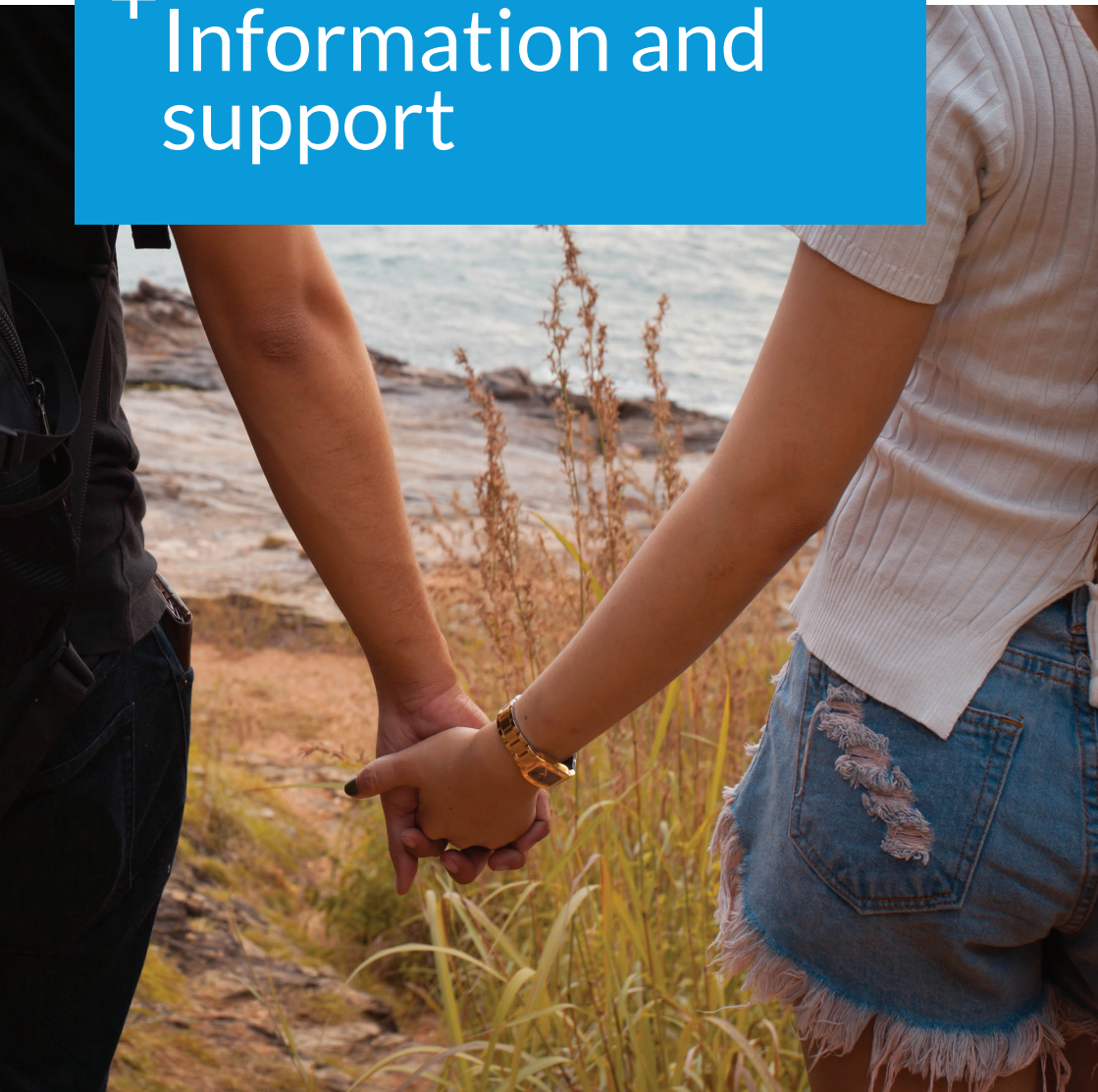
## Emotional support

It is often helpful to speak to other patients with ITP to share experiences and gain emotional support. There are several forums that can help you to do this, as detailed in the next section.





+ Information and support





# + What support is available?

## Associations and support groups

You should try to find out as much as you can about your disease. Talk to your doctor and healthcare team first. In addition to these experts, there are a number of associations and support groups you can also contact.



The ITP Support Association is a UK-registered charity which aims to promote and improve the general welfare of patients, and the families of patients, with ITP by providing patient, parental and antenatal information and support



**Address:** Kimbolton Road, Bolnhurst, Bedfordshire, MK44 2EL, UK

**Telephone:** 01234 376559

**Email:** [info@itpsupport.org.uk](mailto:info@itpsupport.org.uk)



The Platelet Disorder Support Association is dedicated to enhancing the lives of people with ITP and other platelet disorders through education, advocacy, research and support



The Daily Strength website provides the online Thrombocytopenic Purpura Support Group

# + Useful terms



# + Useful terms

<b>Antibodies</b>	Specialised proteins produced by the immune system that attack disease, eg bacteria and viruses. In autoimmune disease, antibodies can be produced that attack the body, as with ITP
<b>Autoimmune disease</b>	When the body's immune system reacts against itself by producing antibodies
<b>Blood clot/clotting</b>	Blood clotting is a process that happens in the body when there is an injury that causes bleeding. A seal (blood clot) is formed over the damaged area which stops the bleeding
<b>Bone marrow</b>	The soft tissue inside of the bones, where blood cells are made
<b>Corticosteroids</b>	Medicines that reduce the activity of the immune system to stop it reacting against the body itself (eg reacting against the platelets, as with ITP)
<b>Idiopathic</b>	A disease or condition that arises spontaneously or for which the cause is unknown
<b>Immune thrombocytopenia (ITP)</b>	Also called immune (idiopathic) thrombocytopenic purpura, ITP is a blood disease where platelets and the special cells which produce platelets are destroyed or damaged by the immune system
<b>Immune system</b>	The tissues and cells that defend the body against infection and disease. The immune system can become directed against the body itself in autoimmune disease
<b>Immunoglobulins</b>	Medicines which reduce the activity of the body's immune system. In ITP, these medicines may help your platelet count improve by stopping the body's immune system from destroying platelets
<b>Immunosuppressants</b>	
<b>Monoclonal antibodies</b>	

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<b>Platelets</b>	Small cells that form blood clots when there is damage to the body that causes bleeding
<b>Refractory</b>	A disease is considered refractory if it has not responded or has stopped responding to treatment
<b>Spleen</b>	An organ that is part of the immune system, which filters, stores and destroys blood cells
<b>Splenectomy</b>	A surgical approach to remove the spleen which removes the site of platelet destruction
<b>Thrombocytopenia</b>	Low platelet count ( $<150 \times 10^9/L$ )
<b>Thrombopoietin (TPO)</b>	A protein produced by the liver that controls platelet production
<b>Thrombopoietin-receptor agonists (TPO-RA)</b>	Medicines that act like your body's natural processes (via the action of thrombopoietin) to increase the number of platelets that are produced



# +References



Nplate® (romiplostim) Patient Information Leaflet. Amgen.



Nplate® (romiplostim) Summary of Product Characteristics (SPC). Amgen.

