

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.

1. Why am I using Mozobil?

Mozobil contains the active ingredient plerixafor. Mozobil is used to improve the release or "mobilisation" of blood stem cells into your blood stream; allowing their collection by apheresis, following which they will be frozen and stored until they are transplanted back to you when you need them to regenerate your bone marrow and blood.

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

2. What should I know before I use Mozobil?

Do not use if you have ever had an allergic reaction to plerixafor 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 Mozobil?](#) in the full CMI.

3. What if I am taking other medicines?

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

See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Mozobil?

- Your medicine will be given to you by a doctor or a nurse in a hospital.
- The dose you will be given will depend on your weight. The usual dose of Mozobil is 240 microgram/kg body weight by subcutaneous injection (under your skin).
- Mozobil should be administered 6 to 11 hours before it is planned to start collecting blood stem cells by apheresis.

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

5. What should I know while using Mozobil?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using Mozobil.• Keep appointments with your treating physician or clinic.• Have any tests when your treating physician says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Mozobil affects you.
Looking after your medicine	<ul style="list-style-type: none">• Your medicine will be stored at the hospital. It should be stored below 25°C.

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

6. Are there any side effects?

Very common side effects include diarrhoea, feeling sick, and injection site redness or irritation. Common side effects include headache, dizziness, feeling tired or unwell, difficulty sleeping, flatulence, constipation, indigestion, vomiting, stomach symptoms such as pain, swelling or discomfort, dry mouth, numbness around the mouth, sweating, generalised redness of the skin, joint pains, pains in the muscles and bones. Serious side effects include swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, hives, fainting, yellowing of the skin and eyes (jaundice), and a pain in the upper left abdomen (belly) or at the tip of your shoulder. If you experience any of these serious side effects, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mozobil. **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 Mozobil.**

Where to find information in this leaflet:

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

1. Why am I using Mozobil?

Mozobil contains the active ingredient plerixafor. Mozobil is in a class of medicines called haematopoietic stem cell mobilisers.

Mozobil is a targeted and reversible blocker of a receptor which is present on many cells in the body, but particularly blood stem cells. Blood stem cells are the cells which give rise to all the cells in your blood - red cells which carry oxygen from the lungs to the tissues; white cells which fight infections, and platelets which stop bleeding. In the case of blood stem cells, this receptor "ties" the blood stem cells to the bone marrow. If this "tie" is broken, the stem cells will float out into the blood flowing in your blood vessels (arteries and veins) where they can then be collected by a process called apheresis. Apheresis involves the insertion of a tube into a vein. Blood is then sucked out into a machine which collects the cells wanted (in your case the stem cells) and the unneeded cells are returned back into your veins.

Mozobil is used to improve the release or "mobilisation" of blood stem cells into your blood stream; allowing their collection by apheresis, following which they will be frozen and stored until they are transplanted back to you when you need them to regenerate your bone marrow and blood.

In studies which have been carried out with Mozobil, it was used with G-CSF (granulocyte-colony stimulating factor), another medicine which is used to mobilise stem cells into the bloodstream.

2. What should I know before I use Mozobil?

Warnings

Do not use Mozobil if:

- you are allergic to plerixafor, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions including
- heart problems
- kidney problems
- high platelet counts
- have a history of feeling faint or lightheaded on standing or sitting or have fainted before upon injections
- if you are under 18 years of age. The effects of Mozobil on children and adolescents have not been studied
- take any medicines for any other condition

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?](#)

Pregnancy and breastfeeding

You should not use Mozobil if you are pregnant.

There are no adequate clinical trials with Mozobil in pregnant women. Tell your doctor if you are, think you may be or are planning to become pregnant.

It is recommended that you use contraception if you are of child-bearing age during Mozobil use and for one week after cessation of treatment.

Men treated with Mozobil should use effective contraception during treatment and for one week after cessation of treatment.

You should not breastfeed if you are being treated with Mozobil.

It is not known if Mozobil is excreted in human milk.

Use in children

There is limited experience with Mozobil in children. Your doctor will discuss the risks and benefits of using Mozobil in children. If you have any questions about using Mozobil ask your doctor.

3. What if I am taking other medicines?

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

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

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

4. How do I use Mozobil?

How much to use

- The usual dose of Mozobil is 240 microgram/kg body weight by subcutaneous injection (under your skin). Mozobil should be administered 6 to 11 hours before it is planned to start collecting blood stem cells by apheresis.
- The dose you will be given will depend on your weight. In order to calculate the dose of Mozobil to be given to you, your weight must be measured. This should be done within a week of your first Mozobil dose. If you have moderate or severe kidney problems, your doctor will reduce the dose.
- Mozobil will be administered given to you by a trained health care professional in a hospital or a clinic.

When to use Mozobil

- It usually only needs to be given on two to four consecutive days, but occasionally has been given for up to 7 consecutive days.
- The treatment with Mozobil will last until enough stem cells have been collected by apheresis for you to be able to have a transplant. In a few cases, enough stem cells may not be collected, and the collection attempt will be stopped.

How to use Mozobil

- The decision to treat you with Mozobil should be made by a doctor experienced in cancers or blood diseases. Your medicine will be given to you by a doctor or a nurse in a hospital. Mobilisation (release of blood stem cells into your blood stream) will be started by first giving you G-CSF per your doctor's recommendation. If you want to know more about G-CSF, please ask your doctor.

If you are given too much Mozobil

There have been no reported overdoses of Mozobil.

Based on data in a small number of patients, doses up to 480 microgram/kg body weight have shown to be safe. If you think you have been given a bigger dose than recommended you should tell your doctor immediately.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention

If too much Mozobil has been injected or it goes into a vein, you may have a serious allergic reaction.

Your treating physician is trained to work out the correct dose and to contact **the Poisons Information Centre** (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), in case of an overdose.

5. What should I know while using Mozobil?

Things you should do

Keep appointments with your treating doctor or clinic.

It is important to have the treatment with Mozobil at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

Have any tests when your treating doctor says to.

You may experience short-lived abnormal blood laboratory results such as a raised white blood cell count or low platelet levels. Your treating doctor may recommend to perform blood tests to monitor your blood cell count.

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

Driving or using machines

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

The effect of Mozobil on your ability to drive a car or operate machinery has not been studied. Make sure that you know how you react to Mozobil before you drive a car or operate machinery or do anything else that may be dangerous if you are dizzy, light-headed, tired or drowsy.

Looking after your medicine

Your medicine will be stored at the hospital.

Store below 25°C.

Once a vial has been opened it must be used immediately or disposed of, because it does not contain any preservative.

The doctor or nurse will check that the product has not passed its expiry date. Mozobil should not be used if there are particles in it.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

Do not use this medicine after the expiry date.

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

Less serious side effects	What to do
Gut related: <ul style="list-style-type: none">• diarrhoea• feeling sick• flatulence• constipation• indigestion• vomiting	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> stomach symptoms such as pain, swelling or discomfort <p>Injection related:</p> <ul style="list-style-type: none"> injection site redness or irritation <p>Muscle, bone and joint related:</p> <ul style="list-style-type: none"> joint pains pains in the muscles and bones <p>Nervous system related:</p> <ul style="list-style-type: none"> headache dizziness numbness around the mouth dry mouth sweating <p>Brain related:</p> <ul style="list-style-type: none"> difficulty sleeping strange dreams and nightmares <p>General side effects:</p> <ul style="list-style-type: none"> feeling tired or unwell generalised redness of the skin 	

Serious side effects

Serious side effects	What to do
<p>Allergic reaction related:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing hives <p>Nervous system related:</p> <ul style="list-style-type: none"> fainting <p>Liver related:</p> <ul style="list-style-type: none"> yellowing of the skin and eyes (jaundice) <p>Spleen related:</p> <ul style="list-style-type: none"> a pain in the upper left abdomen (belly) or at the tip of your shoulder 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Severe gastrointestinal problems like diarrhoea, vomiting, tummy pain and feeling sick are rare.

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.

Heart attacks

In studies, patients with risk factors for a heart attack uncommonly suffered heart attacks after being given Mozobil and G-CSF. It seems unlikely that Mozobil

increases the risk of having a heart attack because only one of these heart attacks occurred close to the use of Mozobil, and most of these patients were known to have risk factors for having a heart attack.

Pins and needles and numbness

Pins and needles and numbness are common in patients being treated for cancers. In the clinical studies carried out with Mozobil and G-CSF compared to G-CSF alone for mobilising blood stem cells, there was no difference in the pins and needles and numbness experienced whether or not the patients were given Mozobil. About one in five

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 in Australia New Zealand at

<https://pophealth.my.site.com/carmreportnz/s/>. 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 Mozobil contains

Active ingredient (main ingredient)	plerixafor
Other ingredients (inactive ingredients)	sodium chloride hydrochloric acid sodium hydroxide (if needed) water for injections

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

What Mozobil looks like

Mozobil is supplied as a solution for injection in a 2.0mL glass vial. Each vial contains 24mg plerixafor in 1.2mL solution. Each pack contains one vial with clear colourless or pale yellow liquid. (Aust R 158423).

Who distributes Mozobil

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Freecall: 0800 283 684
Email: medinfo.australia@sanofi.com

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This leaflet was prepared in May 2025.
mozobil-ccds10-cmiv8-22may25