

MOZOBIL®

(MO-ZY-BILL)

Plerixafor

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mozobil. It does not contain all the available information about Mozobil. It does not take the place of talking to your treating physician or trained health care professional.

All medicines have risks and benefits. Your treating physician has weighed the risks of you taking Mozobil against the benefits they expect it will have.

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

Keep this leaflet.

You may need to read it again.

What it is used for

What Mozobil is used for

Plerixafor 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.

How it works

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.

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.

Ask your treating physician if you have any questions about why it has been prescribed for you.

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

It is not addictive.

Before you are given Mozobil

When you must not be given it

Do not take Mozobil if you have an allergy to:

- any medicine containing (active ingredient)
- any of the ingredients listed at the end of this leaflet.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- kidney problems. Your doctor may adjust the dose
- high platelet counts
- 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.
- you have any other medical condition.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Like most medicines, Mozobil is not recommended during pregnancy or while breastfeeding.

There is no experience with Mozobil in pregnant women. It is recommended that you use

contraception if you are of child-bearing age.

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

Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

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

Tell your treating physician or nurse if you are using other medicines as these medicines may be affected by Mozobil or may affect how well it works (different amounts of these medicines may be needed or different medicines may need to be taken). Your treating physician or nurse will advise you and decide whether or not to give you Mozobil.

How Mozobil is given

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.

How to take it

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.

When it is given

It usually only needs to be given on two to four consecutive days, but occasionally has been given for up to 7 consecutive days.

How long to use it

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.

If you are given too much (overdose)

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 Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) in case of an overdose.

While you are being given Mozobil

Things you must do

Keep appointments with your treating physician 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 physician 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 physician may recommend to perform blood tests to monitor your blood cell count.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your treating physician or nurse as soon as possible if you do not feel well after having Mozobil.

Like all medicines, Mozobil can cause side effects, although not everybody gets them.

Your treating physician has weighed the risks of using this medicine against the benefits they expect it will have for you.

Very common side effects (in more than 1 in 10 patients) include:

- diarrhoea
- feeling sick

- injection site redness or irritation.

Ask your treating physician or nurse to answer any questions you may have.

Tell your treating physician or nurse as soon as possible if you notice any of the following and they worry you:

Common side effects (in fewer than 1 in 10 patients) 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 or the skin
- joint pains
- pains in the muscles and bones.

Abnormal dreams and nightmares have also been reported in patients using Mozobil.

If any of the following happen, tell your doctor immediately or go to your nearest hospital:

- shortly after receiving Mozobil, you experience
 - 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)
- you have a pain in the upper left abdomen (belly) or at the tip of your shoulder.

Other side effects may include:

- Strange dreams and nightmares

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 patients suffered from these feelings.

Patients treated with Mozobil rarely get severe gastrointestinal problems like diarrhoea, vomiting, tummy pain and feeling sick.

Tell your treating physician if you notice any side effects not listed in this leaflet that is making you feel unwell.

Other side effects not listed above may occur.

Storing Mozobil

Storage

Keep out of the reach and sight of children.

Do not store above 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.

Disposal

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.

Product description

What it 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.

Ingredients

Active ingredient:

- plerixafor

Other ingredients:

- sodium chloride, hydrochloric acid, sodium hydroxide (if needed), and water for injections

Supplier

In Australia this product is registered by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

North Ryde NSW 2113

Phone: +61 2 9978 3900

Toll Free Number (medical information): 1800 818 806

Email:

medinfo.australia@sanofi.com

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