Package leaflet: Information for the user

Mozobil 20 mg/ml solution for injection

plerixafor

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mozobil is and what it is used for

Mozobil contains the active substance plerixafor which blocks a protein on the surface of blood stem cells. This protein "ties" blood stem cells to the bone marrow. Plerixafor improves the release of stem cells into the blood stream (mobilisation). The stem cells can then be collected by a machine that separates blood constituents (apheresis machine), and subsequently frozen and stored until your transplant.

If mobilisation is poor, Mozobil is used to help collect blood stem cells from the patient, for collection, storage and reintroduction (transplantation) ,who has lymphoma (a cancer of the white blood cells) or multiple myeloma (a cancer that affects plasma cells in the bone marrow).

2. What you need to know before you use Mozobil

Do not use Mozobil
- if you are allergic to plerixafor or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before using Mozobil.

Tell your doctor:
- if you have or have had any heart problems.
- if you have kidney problems. Your doctor may adjust the dose.
- if you have high white blood cell counts.
- if you have low platelet counts.
- if you 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.

Your doctor may perform **regular blood tests** to monitor your blood cell count.

It is not recommended to use Mozobil for stem cell mobilisation if you have leukaemia (a cancer of the blood or bone marrow).

Other medicines and Mozobil
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
You should not use Mozobil if you are pregnant, since there is no experience with Mozobil in pregnant women. It is important to tell your doctor if you are, think you may be or are planning to become pregnant. It is recommended to use contraception if you are of child-bearing age.

You should not breast-feed if you are using Mozobil, since it is not known if Mozobil is excreted in human milk.

Driving and using machines
Mozobil may cause dizziness and fatigue. Therefore, you should avoid driving if you feel dizzy, tired or unwell.

Mozobil contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Mozobil

Your medicine will be injected by a doctor or a nurse.

You will first receive G-CSF, then you will be given Mozobil
Mobilisation will be started by first giving you another medicine called G-CSF (granulocyte-colony stimulating factor). G-CSF will help Mozobil to work properly in your body. If you want to know more about G-CSF ask your doctor and read the corresponding package leaflet.

How much Mozobil is given?
The recommended dose is 0.24 mg/kg body weight/day. Your dose will depend on your body weight, which should be measured the week before you receive your first dose. If you have moderate or severe kidney problems, your doctor will reduce the dose.

How is Mozobil given?
Mozobil is given by subcutaneous injection (under your skin).

When is Mozobil given for the first time?
You will receive your first dose 6 to 11 hours before apheresis (collection of your blood stem cells).

How long will Mozobil be given?
Treatment lasts 2 to 4 consecutive days (in some cases up to 7 days), until enough stem cells have been collected for your transplant. In a few cases, enough stem cells may not be collected, and the collection attempt will be stopped.

4. Possible side effects

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

Please tell your doctor immediately if
- shortly after receiving Mozobil, you experience rash, swelling around the eyes, shortness of breath or lack of oxygen, feeling lightheaded on standing or sitting, feeling faint or fainting
- you have pain in the upper left abdomen (belly) or your left shoulder

Very common side effects (may affect more than 1 in 10 people)
- diarrhoea, nausea (feeling sick), injection site redness or irritation

Common side effects (may affect up to 1 in 10 people)
- headache
- dizziness, feeling tired or unwell
- difficulty in 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 muscles and bones

Uncommon side effects (may affect up to 1 in 100 people)
- allergic reactions such as skin rash, swelling around the eyes, shortness of breath
- anaphylactic reactions, including anaphylactic shock
- abnormal dreams, nightmares

Rarely, gastrointestinal side effects may be severe (diarrhoea, vomiting, stomach pain and nausea).

Heart attacks
In clinical trials, patients with risk factors for a heart attack uncommonly suffered heart attacks after being given Mozobil and G-CSF. Please inform your doctor immediately if you experience chest discomfort.

Pins and needles and numbness
Pins and needles and numbness are common in patients being treated for cancers. About one in five patients suffered from these feelings. However, these effects do not seem to occur more frequently when you use Mozobil.

You may also have an increase in white blood cells count (leucocytosis), in your blood tests.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via contact details listed below. By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5. How to store Mozobil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial.

This medicine does not require any special storage conditions.

After opening the vial, Mozobil should be used immediately.

Do not throw away any medicines via wastewater or household waste. The pharmacist will throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mozobil contains
- The active substance is plerixafor. Each ml solution for injection contains 20 mg plerixafor. Each vial contains 24 mg plerixafor in 1.2 ml solution.
- The other ingredients are sodium chloride, hydrochloric acid (concentrated) and sodium hydroxide for pH adjustment and water for injections.

What Mozobil looks like and contents of the pack
Mozobil is supplied as a clear colourless or pale yellow solution for injection in a glass vial with a non-latex rubber stopper. Each vial contains 1.2 ml solution.

Each pack contains 1 vial.

Marketing Authorisation Holder
Genzyme Europe B.V., Gooimeer 10, NL-1411 DD Naarden, The Netherlands.

Manufacturer
Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, United Kingdom.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
sanofi-aventis Ireland Ltd T/A SANOFI
Tel: +353 (0) 1 4035 600

Malta
Sanofi Malta Ltd
Tel: +356 21493022

United Kingdom
Sanofi
Tel: +44 (0) 845 372 7101

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.