Package leaflet: Information for the user

Plerixafor 20 mg/ml Solution for Injection

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 Plerixafor is and what it is used for

Plerixafor 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, Plerixafor is used to help collect blood stem cells from the patient, for collection, storage and reintroduction (transplantation):
- in adults who have lymphoma (a cancer of the white blood cells) or multiple myeloma (a cancer that affects plasma cells in the bone marrow)
- in children age 1 to less than 18 years of age with lymphoma or solid tumours.

2. What you need to know before you use Plerixafor

Do not use Plerixafor
- 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 Plerixafor.

Tell your doctor if you:
- have or have had any heart problems
- have kidney problems. Your doctor may adjust the dose
- have high white blood cell counts
- have low platelet counts
- have a history of feeling faint or lightheaded on standing or sitting or have fainted before upon injections

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

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

Other medicines and Plerixafor
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 Plerixafor if you are pregnant, since there is no experience with Plerixafor 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 Plerixafor, since it is not known if Plerixafor is excreted in human milk.

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

Information about ingredient of Plerixafor
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Plerixafor

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

You will first receive G-CSF, then you will be given Plerixafor
Mobilisation will be started by first giving you another medicine called G-CSF (granulocyte-colony stimulating factor). G-CSF will help Plerixafor 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 Plerixafor is given?
The recommended adult dose is either a 20 mg (fixed dose) or 0.24 mg/kg body weight/day.
The recommended dose for children, 1 to less than 18 years of age is 0.24 mg/kg of 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 Plerixafor given?
Plerixafor is given by subcutaneous injection (under your skin).

When is Plerixafor 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 Plerixafor 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 Plerixafor, 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: may affect more than 1 in 10 people
- diarrhoea, nausea (feeling sick), injection site redness or irritation
- low red blood cell count by laboratory test (anaemia in children).

Common: 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: 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 plerixafor 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 Plerixafor.
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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Plerixafor

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. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After opening the vial, Plerixafor 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 Plerixafor 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, and sodium hydroxide for pH adjustment and water for injections.

What Plerixafor looks like and contents of the pack
Plerixafor 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
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer
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This leaflet was last revised in June 2023

PL 00289/2528