1.3.2. Patient Information Leaflet (clean)

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

PLEDITEX solution for injection

(Plerixafor)

Sugar free

Read all of this leaflet carefully before you are given PLEDITEX

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What PLEDITEX is and what it is used for
2. What you need to know before you are given PLEDITEX
3. How to use PLEDITEX
4. Possible side effects
5. How to store PLEDITEX
6. Contents of the pack and other information

1. What PLEDITEX is and what it is used for

PLEDITEX belongs to a group of medicines called immunostimulants.

PLEDITEX 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.

PLEDITEX is used in people with non-Hodgkin's lymphoma or multiple myeloma.

2. What you need to know before you are given PLEDITEX

PLEDITEX should not be administered to you:

- If you are hypersensitive (allergic) to Plerixafor or any of the ingredients of PLEDITEX (listed in section 6).
- If you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection if you:

- have or have had heart problems
- have leukaemia.
- have kidney disease
- have high white blood cell counts
- have low platelet counts
- have a history of feeling faint or lightheaded

To be sure PLEDITEX is not causing harmful effects, your blood will need to be tested often.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before being given this medicine.

Children and adolescents

PLEDITEX has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and PLEDITEX:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

The use of PLEDITEX with these medicines may cause undesirable interactions.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

PLEDITEX must not be taken if you are pregnant or breastfeeding.

Please contact your doctor immediately if you suspect you are pregnant.

Women of childbearing potential have to use effective contraception during treatment.

Driving and using machines

PLEDITEX may influence the ability to drive and use machines. Some patients have experienced dizziness, fatigue or fainting; therefore care is to be taken when driving or operating machines.

It is not always possible to predict to what extent PLEDITEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PLEDITEX affects them.

3. How to use PLEDITEX

PLEDITEX is given as an injection under the skin (subcutaneous) and will only be administered in a hospital or clinic setting by your healthcare professional.

The recommended adult dose is 0,24 mg/kg body weight/day.

Your doctor will decide on the correct dose which will be based on your body mass and condition to obtain the required result.

Before receiving PLEDITEX, you will be given another medication (called granulocyte-colony stimulating factor)) that will help your bone marrow produce stem cells and certain white blood cells that help support your immune system.

You will receive your first dose of PLEDITEX 6 to 11 hours before apheresis (collection of your blood stem cells).

Your doctor will tell you how long your treatment with PLEDITEX will last. Do not stop any treatment unless your doctor tells you to do so.

Treatment lasts 2 to 4 consecutive days (in some cases up to 7 days), until enough stem cells have been collected for your transplant.

If you have the impression that the effect of PLEDITEX is too strong or too weak, tell your doctor or pharmacist.

If you are given more PLEDITEX than you should

Your doctor will administer this medicine and will closely monitor your response and condition and control the dosage. In the unlikely event of overdosage, your doctor will treat the side effects symptomatically.

If you are not given PLEDITEX

Your doctor will ensure you receive PLEDITEX at the correct time. If you are concerned that you may have missed a dose, contact your doctor immediately.

4. Possible side effects

PLEDITEX can have side effects.

Not all side effects reported for PLEDITEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PLEDITEX, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Irregular heart beat
- Allergic reactions (swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause
- difficulty in swallowing or breathing, severe skin rashes)

These are all very serious side effects. If you have them, you may have had a serious reaction to PLEDITEX. You may need urgent medical attention or hospitalisation.

Treatment with PLEDITEX can cause diarrhoea, nausea (feeling sick), injection site redness o

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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

Less frequent side effects:

- allergic reactions such as skin rash, swelling around the eyes, shortness of breath
- anaphylactic reactions, including anaphylactic shock
- abnormal dreams, nightmares, anxiety
- chest discomfort
- pins and needles and numbness
- night or cold sweats or hot flushes

- decreased appetite
- irritability
- nausea
- abnormal heartbeat
- decreased appetite
- swollen eyes
- congestion
- feeling unstable
- taste disturbances

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PLEDITEX.

5. How to store PLEDITEX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PLEDITEX will be stored in the pharmacy

Store at or below 25 °C.

Keep the container in the outer carton in order to protect from light.

Do not use after the expiry date stated on the vial and the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PLEDITEX contains

The active substance is Plerixafor

Each 1,2 mL vial contains 24,0 mg plerixafor 920 mg/mL).

The other ingredients of PLEDITEX are Sodium chloride, Hydrochloric acid, concentrated (pH adjustment), Sodium hydroxide (pH adjustment), Water for injections.

What PLEDITEX looks like and contents of the pack

PLEDITEX is a clear, colourless to pale yellow solution, essentially free from visible particles.

PLEDITEX is supplied in a single-use glass vial Tubular Type – I, 4 ml clear with 13 mm neck stoppered with grey rubber stopper and sealed with aluminium seal having parrot green colour PP disc. The vial will be further packed in pre-printed carton with a package leaflet.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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This leaflet was last revised in

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