



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: ~~17 July 2020~~

Date: 22 March 2022





Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

1.3.2. Patient Information Leaflet (clean)

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

ZAPLEXET solution for injection

(Plerixafor)

Sugar free

Read all of this leaflet carefully before you are given ZAPLEXET

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

1. What ZAPLEXET is and what it is used for

ZAPLEXET belongs to a group of medicines called immunostimulants.



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

ZAPLEXET 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.

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

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

ZAPLEXET should not be administered to you:

- If you are hypersensitive (allergic) to Plerixafor or any of the ingredients of ZAPLEXET (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 ZAPLEXET is not causing harmful effects, your blood will need to be tested often.



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

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

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

Other medicine and ZAPLEXET:

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

The use of ZAPLEXET 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.

ZAPLEXET 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.



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

Driving and using machines

ZAPLEXET 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 ZAPLEXET 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 ZAPLEXET affects them.

3. How to use ZAPLEXET

ZAPLEXET 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 ZAPLEXET, 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 ZAPLEXET 6 to 11 hours before apheresis (collection of your blood stem cells).



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

Your doctor will tell you how long your treatment with ZAPLEXET 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 ZAPLEXET is too strong or too weak, tell your doctor or pharmacist.

If you are given more ZAPLEXET 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 ZAPLEXET

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

4. Possible side effects

ZAPLEXET can have side effects.

Not all side effects reported for ZAPLEXET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZAPLEXET, 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:

Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

- 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 ZAPLEXET. You may need urgent medical attention or hospitalisation.

Treatment with ZAPLEXET can cause diarrhoea, nausea (feeling sick), injection site redness (irritation).

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



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

- 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 ZAPLEXET.

5. How to store ZAPLEXET

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

ZAPLEXET 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.



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

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 ZAPLEXET contains

The active substance is Plerixafor

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

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

What ZAPLEXET looks like and contents of the pack

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

ZAPLEXET 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

AUROGEN SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor



Applicant: Aurogen SA (Pty) Ltd

Product Name: ZAPLEXET

Dosage form and strength: Solution for injection, each 1,2 mL contains 24,0 mg plerixafor

MODULE 1

1.3.2.

Date: 17 July 2020

Date: 22 March 2022

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

This leaflet was last revised in

1. REGISTRATION NUMBER