APPROVED PATIENT INFORMATION LEAFLET FOR MOZOBIL®

Please read this leaflet carefully before using MOZOBIL® solution for injection.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MOZOBIL® (solution for injection)

1. WHAT MOZOBIL® CONTAINS

Active ingredient:

Each vial contains 24,0 mg plerixafor (20 mg/ml).

Inactive ingredients:

Sodium chloride, hydrochloric acid, sodium hydroxide and water for injection.

Each ml **MOZOBIL®** solution for injection contains about 5 mg sodium.

2. WHAT MOZOBIL® IS USED FOR

MOZOBIL® works by helping your bone marrow release stem cells into your bloodstream so they can be collected and transplanted back into the body.

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

3. BEFORE YOU USE MOZOBIL®

Do not use MOZOBIL®

- If you are allergic to plerixafor or to any of the components of **MOZOBIL®** (see **WHAT MOZOBIL® CONTAINS**).

Take special care with MOZOBIL®

- Do not use **MOZOBIL®** if you have leukemia.
- Before you take **MOZOBIL®**, tell your doctor if you have kidney disease.
- To be sure **MOZOBIL®** is not causing harmful effects, your blood will need to be tested often.

Pregnancy and breastfeeding:

DO NOT use **MOZOBIL®** if you are pregnant, planning to become pregnant or breastfeeding. Please contact your doctor immediately if you suspect you are pregnant.

Driving and using machines:

MOZOBIL® is not expected to affect your ability to drive a car or operate machinery. Do take care until you know how this medicine affects you.

Using other medicines with MOZOBIL®:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MOZOBIL®** with these medicines may cause undesirable interactions. Consult your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

4. HOW TO USE MOZOBIL®

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

Your doctor will decide on the correct dose and how long the treatment will be based on you body mass and condition to obtain the required result.

Before receiving **MOZOBIL®**, you will be given another medication that will help your bone marrow produce stem cells and certain white blood cells that help support your immune system.

In the event of an overdosage

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 forget to use your MOZOBIL®

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

5. POSSIBLE SIDE EFFECTS

MOZOBIL® may have side effects.

If you experience the following, please consult your doctor **immediately**, as you may have had an allergic reaction to **MOZOBIL®**:

- 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)

The following common to very common side effects may occur:

- Headache, dizziness, insomnia
- Diarrhoea, constipation, nausea, vomiting
- Flatulence, stomach pain, stomach discomfort, bloatedness, indigestion

- Dry mouth, the loss of sensitivity to pain or touch
- Excessive sweating
- Redness of the skin, pain and swelling at the site were **Mozobil®** was injected
- Joint pain, pain of the muscles, tendons, ligaments and bones, tiredness, a feeling of general discomfort or uneasiness

Not all side effects reported for MOZOBIL® are included in this leaflet.

Should your general health worsen while using this medicine, please consult your doctor for advice.

6. STORAGE AND DISPOSAL OF MOZOBIL®

Store at or below 25 °C.

For single use only. Discard any unused portion.

From a microbiological point of view, once drawn into a syringe, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

KEEP ALL MEDICINE OUT OF REACH OF CHILDREN.

7. PRESENTATION OF MOZOBIL®

2 ml Type 1 clear glass vial with a grey chlorobutyl rubber stopper and an aluminium crimp seal with a blue polypropylene flip-off cap

8. IDENTIFICATION OF MOZOBIL®

Sterile, preservative-free, clear, colourless to pale yellow, pH neutral, isotonic solution.

9. REGISTRATION NUMBER

44/32.2/0546

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

sanofi-aventis south africa (pty) ltd

2 Bond Street

Midrand

11. DATE OF PUBLICATION

September 2011