PATIENT INFORMATION LEAFLET

- Read all of this leaflet carefully before you start taking **NEVIRAPINE MYLAN 200 mg**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **NEVIRAPINE MYLAN 200 mg** 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 AND DOSAGE FORM:

NEVIRAPINE MYLAN 200 mg Tablets

Nevirapine

1. WHAT NEVIRAPINE MYLAN 200 mg CONTAINS:

Each **NEVIRAPINE MYLAN 200 mg** tablet contains nevirapine 200 mg

List of other ingredients: microcrystalline cellulose, povidone (K 30), sodium starch glycolate, colloidal anhydrous silica, magnesium stearate.

Contains 464 mg of lactose monohydrate (sugar)

2. WHAT NEVIRAPINE MYLAN 200 mg IS USED FOR:

NEVIRAPINE MYLAN 200 mg belongs to a group of medicines, known as antiretrovirals. These are used to treat Human Immunodeficiency Virus (HIV) infection. **NEVIRAPINE MYLAN 200 mg** is used in combination with other antiretroviral medicines for the treatment of HIV infection.

NEVIRAPINE MYLAN 200 mg does not cure HIV-1 infection or AIDS.

3. BEFORE YOU TAKE NEVIRAPINE MYLAN 200 mg:

Do not take NEVIRAPINE MYLAN 200 mg:

- If you are allergic to **NEVIRAPINE MYLAN 200 mg** or to any of the ingredients in **NEVIRAPINE MYLAN 200 mg**
- If **NEVIRAPINE MYLAN 200 mg** treatment has previously been discontinued due to severe rash, rash, hypersensitivity syndrome, or clinical hepatitis (inflammation of the liver)
- If you have severe liver disease
- In end-stage renal failure and your are not on haemodialysis
- If you are taking a medicine containing the herbal substance called St John's Wort as it may stop **NEVIRAPINE MYLAN 200 mg** from working properly
- If you are using rifampicin, a medicine to treat tuberculosis
- If you are pregnant or breast-feeding

Take special care with NEVIRAPINE MYLAN 200 mg:

Patients taking NEVIRAPINE MYLAN 200 mg may develop severe liver disease or skin reactions. The risk of these reactions is greatest during the first 18 weeks of treatment, but these reactions can also occur later.

Any patient experiencing severe rash or a rash accompanied by other symptoms such as fever, blistering, lesions in the mouth, "pink eyes", facial swelling, muscle or joint aches, or feeling of general discomfort or uneasiness should discontinue NEVIRAPINE MYLAN 200 mg and consult a doctor. In these patients NEVIRAPINE MYLAN 200 mg must not be restarted.

If your doctor suspects you have NEVIRAPINE MYLAN 200 mg-associated rash, he or she will perform a liver function test.

If you have an allergic reaction to NEVIRAPINE MYLAN 200 mg (characterised by rash with symptoms such as fever, joint pain, muscle pain, and disease of the lymph nodes, plus yellow eyes/skin, changes to the blood cell composition, and kidney dysfunction), NEVIRAPINE MYLAN 200 mg should be permanently stopped and not be re-introduced.

You should NEVER take NEVIRAPINE MYLAN 200 mg as a single treatment; NEVIRAPINE MYLAN 200 mg SHOULD ALWAYS BE TAKEN IN COMBINATION WITH AT LEAST TWO ADDITIONAL ANTIRETROVIRAL AGENTS.

Severe liver dysfunction is a major risk during the first 18 weeks of treatment with **NEVIRAPINE MYLAN 200 mg** and your doctor will monitor you liver function closely. However, severe liver disease can occur after 18 weeks. Therefore monitoring should continue at frequent intervals after this period depending on your status. You should

inform your doctor of any symptoms suggestive of hepatitis (fatigue, fever, abdominal pain, nausea, diarrhoea, appetite loss, depression, yellowing of the skin or whites of the eyes).

The following patients are at increased risk of developing liver problems:

- women
- patients infected with hepatitis B or C
- patients with abnormal liver function tests
- patients who had no previous antiretroviral treatment as well as patients who previously received antiretroviral treatment and had higher CD4 counts at the start of **NEVIRAPINE MYLAN 200 mg** therapy

NEVIRAPINE MYLAN 200 mg will not cure or prevent HIV infection or AIDS; however, it helps keep HIV from reproducing and appears to slow down the destruction of the immune system. **NEVIRAPINE MYLAN 200 mg** will not keep you from spreading HIV to other people.

The long-term effects of **NEVIRAPINE MYLAN 200 mg** are unknown at this time. Combination treatment with **NEVIRAPINE MYLAN 200 mg** has not been shown to reduce the risk of transmission of HIV-1 to others through sexual contact or contaminated blood.

To protect other people from becoming infected with HIV:

- use a condom when you have oral or penetrative sex
- do not risk blood transfer – for example, do not share needles

- **Changes in body fat**. Changes in body fat develop in some patients taking **NEVIRAPINE MYLAN 200 mg**. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts and around the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these fat changes are not known.
- **Opportunistic infections.** Signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment such as **NEVIRAPINE MYLAN 200 mg** is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

- **Changes in bone mineral density** (thinning bones). It is not known whether long term use of **NEVIRAPINE MYLAN 200 mg** will cause damage to the bones. If you have had bone problems in the past, your doctor may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

Taking NEVIRAPINE MYLAN 200 mg with food and drink:

You can take **NEVIRAPINE MYLAN 200 mg** with or without food.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding your baby while taking NEVIRAPINE MYLAN 200 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

Pregnancy:

You must not use **NEVIRAPINE MYLAN 200 mg** during pregnancy.

As oral contraceptives should not be used in HIV infected patients, other means of contraception (such as barrier methods) are recommended in patients being treated with **NEVIRAPINE MYLAN 200 mg.**

Breast-feeding:

You must not use **NEVIRAPINE MYLAN 200 mg** during breast-feeding.

Driving and using machinery:

NEVIRAPINE MYLAN 200 mg may cause dizziness and confusion. If you experience these symptoms while taking **NEVIRAPINE MYLAN 200 mg**, do not drive and do not use any tools or machinery.

Important information about some of the ingredients of NEVIRAPINE MYLAN 200 mg:

NEVIRAPINE MYLAN 200 mg tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **NEVIRAPINE MYLAN 200 mg**.

Taking NEVIRAPINE MYLAN 200 mg with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of NEVIRAPINE MYLAN 200 mg with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases your doctor may want to change the dose.

The following medicines should not be taken with **NEVIRAPINE MYLAN 200 mg:**

- Protease inhibitors e.g. saquinavir, ritanovir, indinavir, nelfinavir and lopinavir/ritanovir (anti-retroviral medicines)
- Ketoconazole (medicine to treat fungal infections)
- Fluconazole (medicine to treat fungal infections)
- Oral contraceptives and other hormonal methods of birth control (it decreases the efficacy of your medicine)
- Methadone (medicine used for treatment of opiate addicts)
- Clarithromycin (decreasing the way your medicine works)
- Rifampicin (medicine to treat tuberculosis)
- Rifabutin (medicine to treat tuberculosis)
- Warfarin (medicine to reduce blood clotting)
- St John's Wort (*Hypericum perforatum*) (medicine to treat depression)

4. HOW TO TAKE NEVIRAPINE MYLAN 200 mg:

Treatment should be prescribed and initiated by a doctor experienced in the management of HIV infection.

Do not share medicines prescribed for you with others.

As **NEVIRAPINE MYLAN 200 mg** must always be taken together with at least two other HIV antiretroviral medicines, you should follow the instructions for your other medicines carefully.

Your doctor will decide on the treatment and dosage of **NEVIRAPINE MYLAN 200 mg** suitable for your condition.
Always take **NEVIRAPINE MYLAN 200 mg** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Only take **NEVIRAPINE MYLAN 200 mg** tablets by mouth, with or without food. Do not chew your tablets.

The dose is one 200 mg tablet per day for the first 14 days of treatment (“lead-in” period). After 14 days, the usual dose is one 200 mg tablet twice a day.

It is very important that you take only one NEVIRAPINE MYLAN 200 mg tablet a day for the first 14 days (“lead-in” period). If you have any rash during this period, do not increase the dose but consult your doctor.

If you take more NEVIRAPINE MYLAN 200 mg than you should:

If you take more medicine than your doctor has told you to, contact a doctor or your nearest hospital casualty department immediately and take your **NEVIRAPINE MYLAN 200 mg** tablets with you. Symptoms of an overdose include swelling, skin inflammation, fatigue, fever, headache, insomnia, nausea, rash, vertigo and vomiting.

If you take more NEVIRAPINE MYLAN 200 mg than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take NEVIRAPINE MYLAN 200 mg:

If you forget to take a dose of **NEVIRAPINE MYLAN 200 mg**, take it as soon as you remember and then continue as before.

Do not take a double dose to make up for missed individual doses.

If you have stopped taking **NEVIRAPINE MYLAN 200 mg** for any reason, especially if you think you are having side- effects, or for another illness, it is important that you contact your doctor before restarting. In some cases you doctor will ask you to restart **NEVIRAPINE MYLAN 200 mg** under direct medical supervision or where medical care can be easily accessed by yourself or others. If your doctor thinks that there is a possibility your symptoms were related to a hypersensitivity reaction, you may be told not to take **NEVIRAPINE MYLAN 200 mg** or any other medicine containing **NEVIRAPINE MYLAN 200 mg** ever again.

5. POSSIBLE SIDE-EFFECTS:

NEVIRAPINE MYLAN 200 mg can have side-effects.

Not all side-effects reported for NEVIRAPINE MYLAN 200 mg are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

The most important side-effects of NEVIRAPINE MYLAN 200 mg are severe and life-threatening skin reactions and serious liver damage. These reactions occur mainly in the first 18 weeks of treatment with NEVIRAPINE MYLAN 200 mg. This is therefore an important period which requires close monitoring by your doctor.

NEVIRAPINE MYLAN 200 mg may cause the following serious side-effects:

- A life threatening allergic reaction referred to as anaphylaxis. Symptoms include but are not limited to, fast or irregular breathing, puffiness or swelling around the face, shortness of breath, a sudden severe decrease in blood pressure, abdominal pain and cramping, anxiety, confusion, cough, diarrhoea, difficulty in swallowing, fainting, light-headedness, dizziness, hives, itchiness, wheezing and blocked nose. This is a medical emergency, call your doctor urgently or rush to the nearest hospital.
- Serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your doctor right away if you get any of the following signs of liver problems:
    - Yellow discolouration of the skin and the white part of your eyeballs
    - Darkening of your urine
    - Your bowel movements turn lighter in colour

- You feel sick to your stomach (nausea)
- You have stomach pain

The following side-effects occur frequently:

- headache
- nausea
- inflammation of the liver, abnormal liver function tests
- rash

Less frequent side-effects are:

- blood disorders
- vomiting, abdominal pain, diarrhoea
- yellowish pigmentation of the skin and eyes
- Stevens-Johnson syndrome (allergic skin reaction), skin hives
- muscle pain
- tiredness, fever

Not all side-effects reported for **NEVIRAPINE MYLAN 200 mg** are included in this leaflet. Should your general health worsen while taking **NEVIRAPINE MYLAN 200 mg**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORAGE AND DISPOSAL OF NEVIRAPINE MYLAN 200 mg:

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Store at or below 30 °C.

Store the tablets in the original container protected from moisture.

Do not remove the blisters from the carton until required for use.

Keep the container tightly closed.

Do not store in bathrooms.

Do not use after the expiry date stated on the label/carton/bottle.

Return all unused medicines to your pharmacist.

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

7. PRESENTATION:

Blister pack of 10 tablets comprises of clear transparent PVC film with backing of aluminium foil coated with heat seal lacquer.

60 **NEVIRAPINE MYLAN 200 mg** tablets packed in a white HDPE bottle with a white opaque polypropylene (PP) screw closure with induction sealing liner and with absorbent cotton.

8. IDENTIFICATION OF NEVIRAPINE MYLAN 200 mg:

White to off-white, biconvex uncoated tablet, debossed with “M107” on one side and scored on both sides.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

46/20.2.8/0005

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

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando, Gauteng,

1601

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

20 April 2012