PROPOSED PATIENT INFORMATION LEAFLET

- Read all of this leaflet carefully before you start taking/using **EFLATEN.**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **EFLATEN** 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

PROPRIETRY NAME AND DOSAGE FORM:

EFLATEN Film-coated Tablets

Tenofovir disoproxil fumarate / Lamivudine / Efavirenz

1. WHAT EFLATEN CONTAINS:

Each film-coated **EFLATEN** tablet contains the active substances tenofovir disoproxil fumarate 300 mg, lamivudine 300 mg and efavirenz 600 mg.

The other ingredients are: microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, sodium lauryl sulfate, sodium chloride, magnesium stearate, lactose monohydrate, film-coat {titanium dioxide, macrogol, talc}

2. WHAT EFLATEN IS USED FOR:

EFLATEN tablets are used in the treatment of the acquired immune deficiency syndrome (AIDS).

EFLATEN will not cure or prevent HIV infection or AIDS; however it helps to keep the HIV virus from reproducing and to slow down the destruction of the immune system. **EFLATEN** will not keep you from spreading HIV to other people.

3. BEFORE YOU TAKE EFLATEN:

Do not take EFLATEN if:

- You are allergic to tenofovir disoproxil fumarate or lamivudine or any of the other ingredients contained in the tablets.
- **EFLATEN** has not been studied in pregnant women. You should not use **EFLATEN** when you are pregnant and breast-feeding. You should use two methods of contraception, whilst you are on treatment with **EFLATEN**. One method should be barrier contraception, such as condoms, and the other method should be an oral or other hormone contraceptive.
- A pregnancy test is recommended before starting treatment.
- It is not known whether **EFLATEN** passes into breast milk.
- You should not breast-feed your infant if you are on treatment with **EFLATEN**.

Do not take the following medicines with **EFLATEN:**

- astemizole, which is an anti-histamine
- cisapride, used to treat gastro-intestinal disorders
- midazolam or triazolam, which is used as a tranquilliser
- pimozide, which is used to treat mental illness
- bepridil, which is used to treat heart disease
- ergot alkaloids, which are used to treat migraines
- St John's Wort (*hypericum perforatum*), a herb used to treat depression
- zalcitabine, used to treat HIV infection

Take special care with EFLATEN:

- If you have bone problems, including previous bone breaks
- If you have liver problems, including hepatitis B infection
- If you have ever had mental illness or are using medicines for mental illness
- If you have ever had seizures or are taking medicines for seizures
- If you are older that 65 years of age
- If you are taking other medicines, as **EFLATEN** may interact with these other medicines
- If you use medicines that may affect your kidney function since use of such medicines in combination with **EFLATEN** will require careful monitoring of your kidney function. Speak to your doctor about this.
- If you have serious nervous system and psychiatric symptoms

EFLATEN does note cure or prevent HIV infection and the changes of still developing infections or illness-associated with HIV is possible. It must be realized that the use of **EFLATEN** does not reduce the risk of transmitting the virus to others through sexual contact or blood contamination.

Taking EFLATEN with food and drink:

EFLATEN must be taken without food.

Pregnancy and breast-feeding:

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

Pregnancy:

If you are pregnant, if you become pregnant, or if you are planning to become pregnant, talk to your doctor about the risks and benefits or taking **EFLATEN**.
If you have taken **EFLATEN** while you were pregnant, your baby may be given extra check-ups to make sure that it is developing normally.

Breast-feeding:

Women who are HIV-positive must not breast-feed because HIV infection can be passed on to the baby in breast-milk. If you are breast-feeding, or thinking about breast-feeding, talk to your doctor immediately.

Driving and using machinery:

EFLATEN can make you dizzy and you can have other side-effects that may make you less alert. Do not drive or operate machinery if you are not feeling well.

Important information about some of the ingredients of EFLATEN:

Tell your doctor if you are lactose-intolerant or intolerant to other sugars.

EFLATEN contains lactose monohydrate. If you know you are lactose-intolerant, or if you have been told that you have intolerance to any other sugars, talk to your doctor before taking **EFLATEN.**

Taking other medicines with EFLATEN:

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

It is important to tell your doctor about all the medicines you are taking or have taken including those you have bought yourself. These include:

- emtricitabine, lamivudine, indinavir, efavirenz, nelfinavir, saquinavir and didanosine, used to treat HIV infection

- trimethoprim/sulphamethoxazole, used to treat fungal and bacterial infections

4. HOW TO TAKE EFLATEN:

Always take **EFLATEN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

Do not suddenly stop taking this medicine without consulting with your doctor first.

EFLATEN must be taken orally on an empty stomach.

Method of administration:

Your doctor will prescribe the correct dosage for you.

If you take more EFLATEN 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 EFLATEN:

If you miss a dose of **EFLATEN**, take it as soon as possible. However if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double dose.

Effects when treatment with EFLATEN is stopped:

You should not stop treatment unless your doctor instructs you to. When your **EFLATEN** supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to **EFLATEN** and become harder to treat.

5. POSSIBLE SIDE-EFFECTS

EFLATEN may have side-effects.

Allergic reactions may occur. If you have any of the following symptoms soon after taking **EFLATEN**, stop taking the medicine and consult your doctor immediately:

- sudden wheeziness and chest pain or tightness
- swelling of face, tongue or throat, which may cause difficulty in swallowing or breathing.
- skin rashes or 'hives' anywhere on the body

Consult your doctor at your next visit if any of the following undesirable events occur:

Frequent:

- dizziness
- headache
- tiredness

Less frequent:

- abnormal thinking
- depression
- confusion
- inability to sleep
- abnormal dreams
- irritability
- forgetfulness

The following may show up in your blood tests:

- *an increase in the level of liver enzymes*
- *an increase in the level to determine inflammation of the pancreas*
- *an increase in cholesterol levels*

LACTIC ACIDOSIS:

Some people who have taken medicines like EFLATEN (nucleoside analogues) have developed a serious condition called lactic acidosis (build up of acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. Call your doctor immediately if you get the following signs or symptoms of lactic acidosis.

- You feel very weak or tired.
- You have unusual (not normal) muscle pain.

- You have trouble breathing.
- You have stomach pain with nausea and vomiting.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a fast or irregular heartbeat.

You may be more likely to get lactic acidosis or liver problems if you are a female, very overweight (obese), or have been taking neucloside analogue medicines, like **EFLATEN**, for a long time.

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

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

6. STORAGE AND DISPOSING OF EFLATEN:

Store at or below 30 ºC. Store in the original container. Do not remove from the carton until required for use.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF EFLATEN:

EFLATEN is packed in high density propylene (HDPE) bottle pack comprising of white opaque wide mouth HDPE bottle with a white opaque polypropylene (PP) screw closure with desiccant packed in an outer carton in 28's, 30's and 100's pack.*

*Not all packs may be marketed

EFLATEN is packed in high density propylene (HDPE) bottle pack comprising of blue opaque wide mouth HDPE bottle with a blue opaque polypropylene (PP) screw closure with desiccant packed in an outer carton in 28's and 30's pack.

8. IDENTIFICATION OF EFLATEN:

White, capsule shaped, film-coated tablets debossed with "M152" on one side and plain on the other side.

9. REGISTRATION NUMBER:

45/20.2.8/0171.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando

Johannesburg, 1609

11. DATE OF PUBLICATION:

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