MODULE 1.3.2: Patient Information Leaflet

Information for the Patient about

CIPLA EFAVIRENZ 600 (Tablets)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CIPLA EFAVIRENZ 600 containing 600 mg **efavirenz** (Tablets).

Read all of this leaflet carefully before you start taking CIPLA EFAVIRENZ 600:

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **CIPLA EFAVIRENZ 600 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.**

WHAT CIPLA EFAVIRENZ 600 CONTAINS:

Each tablet contains 600 mg of efavirenz.

Inactive ingredients are lactose monohydrate, magnesium stearate, Opadry yellow (hypromellose, macrogol, titanium dioxide, yellow iron oxide), povidone, pregelatinised starch, and sodium starch glycollate.

Contains sugar (lactose).

WHAT CIPLA EFAVIRENZ 600 IS USED FOR:

CIPLA EFAVIRENZ 600 tablets are used in combination with other medicines for the treatment of Human Immunodeficiency Virus-1 (HIV-1) infected adults, adolescents and children, weighing 40 kg and above.

BEFORE YOU TAKE CIPLA EFAVIRENZ 600:

Do not take CIPLA EFAVIRENZ 600 if:

- You are known to be allergic (hypersensitive) to **CIPLA EFAVIRENZ 600** or any of its components.
- You are also taking astemizole, cisapride, midazolam, triazolam, pimozide, bepridil, or ergot derivatives (e.g. ergotamine, dihydroergotamine, ergonovine and methylergonovine) because you may develop serious and/or life-threatening adverse events (e.g. abnormal heart rhythms, prolonged sedation or breathing problems) (see **"Taking other medicines with CIPLA EFAVIRENZ 600"**).
- You are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding"**).
- You weigh less than 40 kg.
- You have severely impaired liver function.
- You had a liver disorder or liver failure attributed to treatment with efavirenz, as in **CIPLA EFAVIRENZ 600**.

Do not take St. John's wort in combination with **CIPLA EFAVIRENZ 600**, since this may make **CIPLA EFAVIRENZ 600** less effective and provide the virus with the opportunity to become resistant (less susceptible) to it.

Take special care with CIPLA EFAVIRENZ 600:

If you are taking any other medicines, please inform your doctor before you start taking **CIPLA EFAVIRENZ 600** (see **"Taking other medicines with CIPLA EFAVIRENZ 600"**). Taking **CIPLA EFAVIRENZ 600** if you are also taking *Ginkgo biloba* extracts is not recommended.

CIPLA EFAVIRENZ 600 must not be used as a single medicine to treat HIV or added on as a sole medicine to a failing regimen.

CIPLA EFAVIRENZ 600 does not prevent the risk of passing HIV to others through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others.

If you develop any skin rash while taking **CIPLA EFAVIRENZ 600**, please inform your doctor immediately, especially if you notice blisters on the skin or ulcers inside your mouth. In certain instances your doctor may decide to stop treatment with **CIPLA EFAVIRENZ 600**, while in other instances he/she may prescribe medicines to treat the rash.

Please inform your doctor if you previously required stopping treatment with other antiretroviral medicines due to a skin rash.

Treatment with **CIPLA EFAVIRENZ 600** may cause you to act or think inappropriately (including acting aggressively) or to feel depressed. If you are known to have mental illness, please inform your doctor before you start taking **CIPLA EFAVIRENZ 600**, because you may have an increased risk of experiencing such

side effects (see **"POSSIBLE SIDE EFFECTS"**). Severe depression, including thoughts about suicide, may also occur. Please report to your doctor immediately if you experience any of these side effects.

CIPLA EFAVIRENZ 600 may cause dizziness, sleeplessness, sleepiness, impaired concentration and abnormal dreams in the first one or two days of starting treatment. These symptoms generally resolve after the first 2 – 4 weeks and are likely to improve with continued treatment.

Please inform your doctor if you are known to have epilepsy and/or if you are taking medicines for epilepsy. You may have to go for blood tests at regular intervals to monitor your blood levels of such medicines.

If you have liver problems, you must not take **CIPLA EFAVIRENZ 600** (see **"Do not take CIPLA EFAVIRENZ 600 if"**). Please inform your doctor if you have been diagnosed with liver problems in the past or if you are known to have liver disease, including hepatitis B or C infection, or if you are taking other medicines. You may have to go for regular blood tests to monitor your liver function and bleeding tendencies.

Side effects of the liver leading to liver failure, liver transplant or death have occurred and therefore your doctor may monitor your liver function even if you have never suffered from liver disease before. These side effects may occur many months after treatment with **CIPLA EFAVIRENZ 600** has stopped and is more likely to occur in younger people, people with low CD4+ counts and in women.

If you experience yellowing of the eyes or skin (jaundice) you should report to your doctor immediately. You may need to stop taking **CIPLA EFAVIRENZ 600**, and your doctor may continue to monitor your liver function for several months.

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment 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 (e.g. fever, chills, coughing, etc.), please inform your doctor immediately.

Redistribution, accumulation, or loss of body fat may occur in people taking **CIPLA EFAVIRENZ 600**. You may develop excess fat on your abdomen (stomach), behind your neck, or your breasts may enlarge, while your legs and arms become thinner. Contact your doctor as soon as possible if you notice changes in body fat distribution. You may require blood tests to monitor your cholesterol and blood sugar (glucose) levels.

Please report to your doctor as soon as possible if you experience stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. These symptoms may be due to a bone disease called osteonecrosis (loss of bone).

You will have to go for periodic blood tests to check your cholesterol and blood lipid levels while you are taking **CIPLA EFAVIRENZ 600**.

If you have severely impaired kidney function, your doctor will monitor you while you are taking **CIPLA EFAVIRENZ 600**.

If you are elderly, you should inform your doctor as you will have to be monitored for the correct dosage.

CIPLA EFAVIRENZ 600 is not recommended for children weighing less than 40 kg and the frequency of rash is increased in children.

Taking CIPLA EFAVIRENZ 600 with food and drink:

Taking **CIPLA EFAVIRENZ 600** with or after food, or with grapefruit juice, increases the blood concentrations of efavirenz with a possible increase in side effects (see **"POSSIBLE SIDE EFFECTS"**). It is recommended that you take **CIPLA EFAVIRENZ 600** on an empty stomach, preferably at bedtime, and to avoid grapefruit juice (see **"HOW TO TAKE CIPLA EFAVIRENZ 600"**).

Pregnancy and breastfeeding:

Do not take **CIPLA EFAVIRENZ 600** if you are pregnant (see **"Do not take CIPLA EFAVIRENZ if"**). If your doctor has prescribed **CIPLA EFAVIRENZ 600**, you should make use of effective contraception, which should include the use of barrier contraceptives (e.g. condoms). You will have to use effective contraception during

treatment and up to 12 weeks after stopping treatment. You may have to go for a pregnancy test before you start treatment with **CIPLA EFAVIRENZ 600**.

Mothers should not breastfeed their infants while taking **CIPLA EFAVIRENZ 600**. In general, women infected with HIV should not breastfeed their infants in order to avoid transmission of HIV to their babies.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking CIPLA EFAVIRENZ 600.

Driving or using machinery:

CIPLA EFAVIRENZ 600 may cause dizziness, impaired concentration, and/or drowsiness. You should refrain from driving a car or operating machinery until you know how **CIPLA EFAVIRENZ 600** affects you.

Important information about some of the ingredients in CIPLA EFAVIRENZ 600:

CIPLA EFAVIRENZ 600 contains lactose. If you have been diagnosed with the rare hereditary condition of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption, you should not take **CIPLA EFAVIRENZ 600**. Lactose may also have an effect on the control of your blood sugar if you have diabetes mellitus. Please discuss this with your doctor.

Taking other medicines with CIPLA EFAVIRENZ 600:

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

Please discuss the use of the following with your doctor or pharmacist, as you may require a dose adjustment or special precaution:

- Any other medicines for the treatment of HIV-1 infection including:
    - A fixed dose combination tablet containing tenofovir, emtricitabine and efavirenz.
    - Protease inhibitors, such as indinavir, ritonavir, atazanavir, saquinavir, darunavir or lopinavir.
    - Maraviroc.
    - Raltegravir.
    - Other non-nucleoside reverse transcriptase inhibitors (NNRTIs), such as nevirapine or delavirdine.
- St. John's wort used for depressed mood (see **"Do not take CIPLA EFAVIRENZ 600 if"**).
- Grapefruit juice.
- *Ginkgo biloba* extracts (see **"Take special care with CIPLA EFAVIRENZ 600"**).
- Cisapride, midazolam, triazolam, pimozide, bepridil or ergot derivatives (e.g. ergotamine, dihydroergotamine, ergonovine and methylergonovine) (see **"Do not take CIPLA EFAVIRENZ 600 if"**).
- Boceprevir, telaprevir, simeprevir for the treatment of hepatitis C.
- The following antibiotics: clarithromycin, azithromycin, erythromycin.
- Rifampicin or rifabutin for the treatment of tuberculosis.
- Medicines to treat fungal infections, such as itraconazole, posaconazole, voriconazole and ketoconazole.

- Artemether and lumefantrine, or atovaquone and proguanil for the prevention of malaria.
- Warfarin, a blood thinner.
- Medicines to treat epilepsy, such as carbamazepine, phenytoin, phenobarbitone, or valproic acid.
- Antidepressants, such as sertraline or bupropion.
- Diltiazem, verapamil, felodipine, or nifedipine to treat high blood pressure or abnormal heart rhythms.
- Cholesterol-lowering medicines, such as atorvastatin, pravastatin or simvastatin.
- Oral contraceptives (the pill), injectable contraceptives or oestrogen implants.
- Ciclosporin, tracrolimus or sirolimus to suppress the immune system.
- Methadone, buprenorphine/naloxone to treat opiate withdrawal.
- Cannabinoid tests to detect the use of dagga/marijuana.
- Alcohol or medicines for mental illness, as it is possible that you may experience increased depression of the central nervous system. Please ask your doctor for advice.

HOW TO TAKE CIPLA EFAVIRENZ 600:

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

Always take CIPLA EFAVIRENZ 600 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one **CIPLA EFAVIRENZ 600** tablet once daily on an empty stomach, preferably in the evening. A high fat meal may increase the absorption of **CIPLA EFAVIRENZ 600** and must be avoided.

To lessen the burden of nervous system side effects, bedtime dosing is recommended during the first two to four weeks of treatment and if you continue to experience such side effects (see **"POSSIBLE SIDE EFFECTS"**).

CIPLA EFAVIRENZ 600 should only be taken if you weigh 40 kg or more. Since **CIPLA EFAVIRENZ 600** is not scored, the tablet should not be halved.

Your doctor will decide how long treatment with **CIPLA EFAVIRENZ 600** will last. Do not stop taking **CIPLA EFAVIRENZ 600** without discussing it with your doctor.

If you have the impression that the effect of **CIPLA EFAVIRENZ 600** is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPLA EFAVIRENZ 600 than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side effects such as listed below (see **"POSSIBLE SIDE EFFECTS"**).

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

If you forget to take CIPLA EFAVIRENZ 600:

It is important that you do not miss any doses. If you miss a dose of **CIPLA EFAVIRENZ 600**, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule of one tablet once daily. Do not take a double dose to make up for a forgotten individual dose.

POSSIBLE SIDE EFFECTS:

CIPLA EFAVIRENZ 600 can have side-effects.

Not all side effects reported for CIPLA EFAVIRENZ 600 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLA EFAVIRENZ 600 please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **CIPLA EFAVIRENZ 600** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hives, itching, skin rash, swelling of the lips, tongue or face, or any other symptom you think may be due to an allergic reaction.
- Yellow discolouration of the skin or whites of the eyes, with pain over the liver area.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CIPLA EFAVIRENZ 600**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Those that occur frequently:

- Any skin rash.

- Those that occur less frequently:
  - Elevated (very happy) mood, hearing or seeing things that are not real, paranoia, thoughts about suicide or death, inappropriate behaviour, delusions or delirium (see **"Take special care with CIPLA EFAVIRENZ 600"**).
  - Reduced sense of touch, memory loss, abnormal gait or abnormal thinking.
  - Seizures (fits).
  - State of unconsciousness (stupor).
  - Severe stomach pain accompanied by vomiting, distension of the stomach, fever, and loss of appetite (pancreatitis).
  - Blisters on the skin.

- Those that occur with unknown frequency:
  - Pins and needles, pain in the hands or feet, speech disorders.
  - Palpitations or rapid heart rate.
  - Tightness of the chest, shortness of breath or wheezing.
  - Hives.
  - Muscle weakness with dark coloured urine and/or fever (myopathy).
  - Fainting spells.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Those that occur frequently:
  - Abnormal dreams, anxiety, depression or sleeplessness.

- Disturbances of balance, disturbance in attention, dizziness, impaired concentration, sleepiness or headache.
- Nausea, vomiting, loose stools (diarrhoea), or stomach pain.
- Itching, increased sweating.
- Fatigue or pain.

- Those that occur less frequently:
  - Struggling to exert control over your emotions, aggression, confusion, anxiety or fear.
  - Loss of appetite, agitation, abnormal coordination, tremor.
  - Blurred vision.
  - Ringing in the ears or a sensation that the world is spinning or moving.
  - Flushing of the skin.
  - Indigestion.
  - Breast enlargement.
- Those that occur with unknown frequency:
  - Weight gain or weight loss.
  - Depression, emotional instability.
  - Apathy, increased appetite, impotence, decreased or increased libido, taste disturbance.
  - Hot flushes.
  - Pain over the sinuses with the production of phlegm, or symptoms of a cold or the flu.
  - Constipation, heartburn or acid reflux.
  - Acne, hair loss, dry skin, nail disorders, or skin discolouration.
  - Muscle or joint pain.

- Alcohol intolerance, extreme tiredness or weakness, or a general feeling of being unwell.
- Abnormal distribution of body fat (see **"Take special care with CIPLA EFAVIRENZ 600"**).

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

STORING AND DISPOSING OF CIPLA EFAVIRENZ 600:

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CIPLA EFAVIRENZ 600:

Available in white plastic bottles containing 28 or 30 tablets.

IDENTIFICATION OF CIPLA EFAVIRENZ 600:

Yellow-coloured, capsule-shaped, biconvex tablets debossed with "EFV" on one side and plain on other side.

REGISTRATION NUMBER:

41/20.2.8/0106 – South Africa

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO MANUFACTURING (PTY) LTD

1474 South Coast Road

Mobeni

Durban

4052

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