PROPOSED CLEAN PATIENT INFORMATION LEAFLET

PRIPREMA

SCHEDULING STATUS:

S4

PRIPREMA

(Emtricitabine 200 mg and tenofovir alafenamide 25 mg film-coated tablets)

Sugar free

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care professional.
- PRIPREMA 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 is in this leaflet

1. What PRIPREMA is and what it is used for

Emtricitabine and tenofovir are medicines that terminate formation of viral genetic material (DNA) by inhibiting the reverse transcriptase enzyme, which is responsible for viral DNA synthesis.

PRIPREMA is used in combination with other antiviral medicines for the treatment of HIV-1 infection in adults and adolescents (aged 12 years and older with body weight of at least 35 kg).

2. What you need to know before you take PRIPREMA

Do not take PRIPREMA:

- If you are allergic to emtricitabine, tenofovir or any of the other ingredients of PRIPREMA listed in section 6
- If you are pregnant or breastfeeding your child.

Warnings and precautions

The current anti-retroviral therapy does not prevent the risk of transmitting HIV through sexual contact or blood contamination. Ensure that you make use of barrier contraception (e.g., condoms) during sexual intercourse to prevent the unnecessary spreading of the virus.

Take special care with PRIPREMA:

- If you are infected with HIV as well as hepatitis B or C as PRIPREMA may cause fatal side effects to your liver.
- If you have liver disease, as using PRIPREMA may cause a condition known as hepatomegaly (enlarging of your liver).
- PRIPREMA may cause you to gain weight and increase the levels of glucose (sugar) and lipids (fats) in your blood.
- PRIPREMA may cause mitochondrial dysfunction (when your cells do not work properly) which may result in blood disorders such as anaemia (decreased red blood cell count), neutropenia (decrease in white blood cell count), nerve damage and metabolic disorders.
- PRIPREMA may initially affect your immune system causing you to develop opportunistic infections (such as the common cold). You should remain under close monitoring by your doctor as he will need to treat these infections as well as monitor your CD4 count and viral load.
- If you are infected with HIV-1 and have the K65R mutation.
- If you have advanced HIV-disease, you may be at risk of developing bone death while taking PRIPREMA. You should consult your doctor immediately if you start to experience joint aches and pain, joint stiffness or difficulty in moving while taking PRIPREMA.
- PRIPREMA may cause damage to your kidneys.
- If you have kidney failure.

- If you are taking other medicines for treating HIV infection, such as atazanavir, lopinavir and darunavir.
- If you are taking medicines to treat seizures such as carbamazepine, oxcarbazepine, phenobarbitone and phenytoin.
- If you are taking medicines known as antimycobacterials, which are used to treat TB, such as rifampicin, rifabutin and rifapentine.
- If you are taking a medicine known as boceprevir as well as a herbal product called St. john's wort. Please inform your doctor if you are taking any other medicines in addition to all those listed above.

Children

Children must not take PRIPREMA.

Other medicines and PRIPREMA

Always tell your health care provider if you are taking any other medicine. This includes all complementary and traditional medicines.

Tell your doctor if you are taking any of the following:

- Other medicines for treating HIV-1 infection, such as atazanavir, cobicistat, ritonavir, darunavir etc.
- If you are taking medicines that are eliminated by your kidneys and these may increase the concentration of emtricitabine, one of the components of PRIPREMA, in your body.

- If you are taking medicines that are known as P-gp inducers e.g., rifampicin, rifabutin, carbamazepine and phenobarbital, as they are expected to cause a decrease in tenofovir alafenamide absorption, one of the components of PRIPREMA, which may cause you to develop resistance to PRIPREMA.
- If you are taking medicines known as P-gp inhibiters e.g., cobicistat, ritonavir and ciclosporin, as they are expected to increase the absorption of tenofovir alafenamide.
- If you are taking medicines used to treat fungal infections e.g., ketoconazole, itraconazole, fluconazole, isavuconazole.
- If you are taking antimycobacterials, medicines used to treat TB, such as rifabutin, rifampicin and rifapentine, as they may cause you to develop resistance to PRIPREMA.
- If you are taking medicine to treat hepatitis C infection e.g., ledipasvir, sofosbuvir, velpatasvir, voxilaprevir
- If you are taking medicines to control seizures e.g., oxcarbazepine, phenobarbitone, phenytoin and carbamazepine.
- If you are taking medicine to treat depression e.g., sertraline.
- If you are taking herbal products known as St. John’s wort.
- If you are taking immunosuppressants e.g., ciclosporin.
- If you are taking oral contraceptives e.g., norgestimate or Ethinylestradiol.
- If you are taking sedatives (medicines used to help you sleep) e.g., midazolam.

PRIPREMA with food and drink

PRIPREMA may be taken with or without food.

Pregnancy and breastfeeding

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 professional for advice before taking PRIPREMA.

Do not take PRIPREMA if you are pregnant or breastfeeding.

Driving and using machines

PRIPREMA can cause dizziness and therefore negatively influence your ability to drive and use machines. You need to be aware of how PRIPREMA affects you before you engage in such activities.

3. How to take PRIPREMA

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

Always take PRIPREMA exactly as described in this leaflet or as your doctor or pharmacist or nurse told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is one tablet once daily, with or without food. Do not chew, crush or split the tablet.

If you take more PRIPREMA you should

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

If you forget to take PRIPREMA

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

If you miss a dose of PRIPREMA within 18 hours of the time it is usually taken, then take your dose as soon as possible and resume your normal dosing schedule. If you miss a dose of PRIPREMA by more than 18 hours, then do not take the missed dose and simply resume your normal dosing schedule. If you vomit within 1 hour of taking PRIPREMA, another tablet should be taken.

4. Possible side effects

PRIPREMA can have side effects.

Not all side effects reported for PRIPREMA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRIPREMA, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Abnormal dreams
- Headache
- Dizziness
- Nausea
- Diarrhoea
- Vomiting
- Abdominal pain
- Flatulence
- Fatigue.

Less frequent side effects

- Anaemia (decreased red blood cell count)
- Dyspepsia (indigestion or heartburn)
- Arthralgia (joint pain).

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. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of PRIPREMA.

You may also report any suspected side effects (to Cipla Medpro (Pty) Ltd.) by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

5. How to store PRIPREMA

Store in the original container at or below 30 °C.

Keep the bottle tightly closed.

Store all medicines out of reach 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).

6. Contents of the pack and other information

What PRIPREMA contains

Each tablet contains 200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide as active ingredients.

Inactive ingredients: Croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry II white 85F18422 [macrogol (polyethylene glycol) (E1521), polyvinyl alcohol-part hydrolysed (E1203), talc (E553b), titanium dioxide (E171)].

What PRIPREMA looks like and contents of the pack

White to off white coloured, capsule shaped, biconvex film-coated tablet debossed with 'Cipla' on one side and plain on other side.

PRIPREMA is packed in a white high density polyethylene (HDPE) bottle that is fitted with a white HDPE closure, containing 28, 30 or 90 film-coated tablets and silica gel desiccants.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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Registration number

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR code to be generated and included after approval