1.3.2. PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

TRUVADA

Film-coated tablets

Read all of this leaflet carefully before you start taking TRUVADA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TRUVADA 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 TRUVADA CONTAINS

The active substances of TRUVADA are emtricitabine and tenofovir disoproxil fumarate.

Each film-coated tablet contains 300 mg of tenofovir disoproxil fumarate (which is equivalent to 245 mg tenofovir disoproxil) and 200 mg of emtricitabine.

The other ingredients are croscarmellose sodium, FD&C blue no.2, indigo carmine lake (CI no. 73015), hypromellose (hydroxypropyl methylcellulose 2910), lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, titanium dioxide (CI no. 77891), triacetin

Contains sugar: Lactose monohydrate 96,00 mg

WHAT TRUVADA IS USED FOR

TRUVADA is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analogue reverse transcriptase inhibitor (NRTI). TRUVADA contains 2 medicines, emtricitabine (200 mg) and tenofovir disoproxil fumarate (or tenofovir DF) (300 mg) combined in one pill.

Treatment for HIV Infection

TRUVADA is used in adults in combination with other anti-HIV medicines to treat people with HIV infection.

Treatment for Pre-Exposure Prophylaxis (PrEP)

To reduce the risk of getting HIV-1 in adults, TRUVADA is to be used in combination with safer sex practices and rigorous use at all times. This is called Pre-Exposure Prophylaxis or PrEP.

BEFORE YOU TAKE TRUVADA

Do not take TRUVADA:

- If you are hypersensitive (allergic) to emtricitabine or tenofovir disoproxil fumarate or any of the other ingredients of TRUVADA (see WHAT TRUVADA CONTAINS).
- If you are pregnant or breastfeeding.
- If you have kidney problems or are on dialysis.
- If you are already taking any other tenofovir or emtricitabine containing medicines or medicines containing lamivudine because these medicines contain the same or similar active ingredients.
- If you are a female who is taking TRUVADA to prevent HIV infection and you become pregnant while taking TRUVADA.
- If you are HIV positive or if your HIV status is not known, when using TRUVADA to prevent HIV infection.
- If you are not fully committed to use TRUVADA every day for Pre-Exposure Prophylaxis.

See the section "WHAT TRUVADA IS USED FOR" and talk to your healthcare provider for more information about how to prevent HIV infection.

Take special care with TRUVADA:

- If you have bone problems.
- If you have liver problems including Hepatitis B Virus infection.
- If you have had kidney problems in the past or take other medicines that can cause kidney problems.
- If you are taking other medicines as TRUVADA may interact with these other medicines.
- **If you are also infected with the Hepatitis B Virus (HBV),** you need close medical follow up for several months after stopping treatment with TRUVADA. Follow-up includes medical examinations and blood tests to check for HBV that could be getting worse.
- **Patients with Hepatitis B Virus who take TRUVADA and then stop it, may get "flare-ups" of their hepatitis.** A "flare-up" is when the disease suddenly returns in a worse way than before. TRUVADA is not approved for the treatment of Hepatitis B Virus infection.

You should read the patient information leaflet of the other HIV medicines that you will be taking in combination with TRUVADA.

- Changes in body fat have been seen in some patients taking TRUVADA and other anti-HIV medicines. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effect of these conditions are not known at this time.
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking TRUVADA and other HIV medicines. Your immune system may get

stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having any new symptoms after starting your HIV medicine.

Some people who have taken medicine like TRUVADA have developed a serious condition called lactic acidosis (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital (see POSSIBLE SIDE EFFECTS).

The following side effects may be signs of lactic acidosis:

- deep rapid breathing
- drowsiness
- feeling sick (nausea), being sick (vomiting) and stomach pain

Some people who have taken medicines like TRUVADA have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

Any child exposed *in utero* to nucleoside and nucleotide analogues (like TRUVADA) even HIV negative children, should have clinical and laboratory follow up and should be fully investigated for possible mitochondrial dysfunction.

If you are diabetic, overweight or have high cholesterol, talk to your doctor.

Other important information to know before taking TRUVADA for HIV-1 treatment:

- You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.
- **TRUVADA does not cure HIV.** If you already have HIV or get HIV and take TRUVADA by itself without other medicines, you may develop resistance to TRUVADA. This means that

the HIV virus may become harder to treat.

- TRUVADA does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safe sex.
- You may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak.

Some of these conditions are different forms of tuberculosis infection, a form of pneumonia, herpes virus infections and a form of meningitis (infection of the protective membranes surrounding the brain and spinal cord).

Other important information to know before taking TRUVADA to help prevent you from getting HIV:

- **You must get tested to be sure you are HIV-negative.** It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking TRUVADA. Ask your partner to get tested. Know the HIV status of your partner.
- TRUVADA may not always keep you from getting HIV.
- **You must still practice safe sex at all times. Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- **You must also use other prevention methods to keep from getting HIV.**
- Get information and support to help reduce risky sexual behaviour.
- Have fewer sex partners.
- **Do not miss any doses of TRUVADA. Missing doses increases your risk of getting HIV.**

Other important information to know before taking TRUVADA to help prevent you from

getting HIV or for HIV-1 treatment:

Avoid doing things that can increase your risk of spreading HIV infection to other people if you are HIV-infected, or increase your risk of acquiring HIV if you are taking TRUVADA for prevention. These include:

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Tell your healthcare provider if you have any of the following symptoms within the last month before you start taking TRUVADA or at any time while taking TRUVADA:

- tiredness
- fever
- sweating a lot (especially at night)
- rash
- vomiting
- diarrhoea
- joint or muscle aches
- headache
- sore throat
- enlarged lymph nodes in the neck or groin.

These may be signs of HIV infection and you may need to have another test to diagnose HIV. Also, tell your healthcare provider if you think you were recently exposed to the HIV virus. If you are already taking TRUVADA to prevent HIV-1 infection, your healthcare provider may tell you

to stop taking TRUVADA until an HIV test confirms that you do not have HIV-1 infection.

Taking TRUVADA with food and drink

TRUVADA may be taken with or without a meal. Take TRUVADA at the same time each day.

Pregnancy and breastfeeding

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

- Do not use TRUVADA if you are pregnant. The effects of TRUVADA on pregnant women or their unborn babies are not known.
- A reliable method of contraception should be used to avoid pregnancy while taking TRUVADA.
- Do not breastfeed if you are taking TRUVADA. Do not breastfeed if you have HIV. If you are a woman who has or will have a baby, talk to your healthcare provider about the best way to feed your baby. If your baby does not already have HIV, there is a chance that the baby can get HIV through breastfeeding.

Driving and using machinery

TRUVADA can make you dizzy, so care should be taken when driving or using machinery.

Important information about some of the ingredients in TRUVADA

TRUVADA contains lactose. If you have been told by your doctor that you have lactose intolerance, contact your doctor before taking TRUVADA.

Taking other medicines with TRUVADA

Always tell your healthcare professional if you are taking any other medicine. (this includes

complementary or traditional medicines). Especially tell your healthcare professional if you take:

- Other medicines that contain tenofovir DF, emtricitabine or lamivudine, either alone or in combination. **TRUVADA should not be used with those medicines because they contain the same or similar active ingredients as TRUVADA (see "Do not take TRUVADA").**
- Medicines that contain didanosine. Tenofovir DF (a component of TRUVADA) may increase the amount of didanosine in your blood. **You may need to visit your healthcare professional more regularly if you are taking TRUVADA and didanosine together.** The dose of didanosine may also need to be reduced.
- Atazanavir sulphate or lopinavir and ritonavir co-formulation. These medicines may increase the amount of tenofovir DF (a component of TRUVADA) in your blood, which could result in more side effects. You may need to visit your healthcare professional more regularly if you are taking TRUVADA and atazanavir sulphate or lopinavir and ritonavir co-formulation together. TRUVADA may decrease the amount of atazanavir sulphate in your blood. If you are taking TRUVADA and atazanavir sulphate together, you should also be taking ritonavir.
- Ledipasvir and sofosbuvir or sofosbuvir and velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir co-formulation or adefovir dipivoxil. These medicines used for a liver disease, called hepatitis C or B, may increase the amount of tenofovir DF (a component of TRUVADA) in your blood, which could result in more side effects.

Keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all of your healthcare providers and pharmacist every time you visit your healthcare provider or fill a prescription.

HOW TO TAKE TRUVADA

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

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

Recommended dosage of TRUVADA tablets:

The usual dose of TRUVADA is one (1) tablet once a day.

Take TRUVADA at the same time each day.

Treatment of HIV

If you take TRUVADA for the treatment of HIV infection, it should be used in combination with other anti-HIV medicines.

Prevention of HIV

If you take TRUVADA to reduce the risk of getting HIV-1, you must also use other methods to reduce your risk of getting HIV. See "Take special care with TRUVADA".

Your doctor will tell you how long your treatment with TRUVADA will last. Do not stop treatment early.

If you have the impression that the effect of TRUVADA tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more TRUVADA than you should

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/missed a dose of TRUVADA

It is important that you do not miss any doses. If you miss a dose of TRUVADA, take it as soon as possible that day and then take your next scheduled dose at its regular time. If it is almost time for your next dose, **do not** take 2 doses at the same time. Contact your healthcare provider or pharmacist if you are not sure what to do. Do not take more than one dose of TRUVADA in a day.

Effects when treatment with TRUVADA is stopped

You should not stop treatment unless your doctor instructs you to. When your TRUVADA 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 will increase if the medicine is stopped for even a short time. The virus may develop resistance to TRUVADA and become difficult to treat.

POSSIBLE SIDE EFFECTS

TRUVADA can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (angioedema);
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRUVADA. 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:

- Difficulty breathing;
- less urine than is normal for you;
- signs or symptoms of lactic acidosis (build-up of acid in the blood) e.g. feeling weak or tired, having unusual muscle pain, trouble breathing, stomach pain with nausea and vomiting, feeling cold (especially in your arms and legs), feeling dizzy and lightheaded and having a fast or irregular heartbeat;
- signs or symptoms of serious liver problems e.g. skin or white part of the eye turns yellow (jaundice), urine turns dark, stools turn light in colour, feeling sick to your stomach (nausea), have lower stomach area pain (abdominal pain) and not feeling like eating food for several days or longer;
- signs of softening of the bones (bone pain and sometimes resulting in fractures).

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Stomach pain;
- pain;
- abnormal physical weakness or lack of energy;
- diarrhoea;
- headache;
- nausea (feeling sick), vomiting;

- dizziness;
- difficulty sleeping, abnormal dreams;
- problems with digestion resulting in discomfort after meals, feeling bloated, flatulence;
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin which may be allergic reactions), itching, changes in skin colour including darkening of the skin in patches;
- other allergic reactions e.g. wheezing, swelling or feeling lightheaded.

Blood tests may also show:

- Low white blood cell count (a reduced white blood cell count can make you more prone to infection);
- increased triglycerides (fatty acids), bile or sugar in the blood;
- increased creatine kinase (an enzyme resulting from breakdown of your muscles);
- increased amylase or lipase in the blood;
- increased liver enzymes.

The following side effects have been reported with unknown frequency:

- Back pain caused by kidney problems;
- anaemia (low red blood cell count), which may include symptoms e.g. fatigue, skin pallor, shortness of breath, light-headedness, dizziness, or a fast heartbeat;
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells;
- inflammation of the pancreas which most commonly begins with abdominal pain in the middle or upper left part of the abdomen and may increase after eating or lying flat the back.

Blood and urine tests may also show:

- Decreases in potassium in the blood;
- decreases in phosphate in the blood;
- increased creatinine in your blood;
- changes to your urine.

This list of side effects is not complete. If you have questions about side effects, ask your healthcare provider. You should report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

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

STORING AND DISPOSING OF TRUVADA

- Store TRUVADA at or below room temperature (at or below 30 °C). It should remain stable until the expiration date printed on the label.
- Do not keep your medicine in places that are too hot or cold.
- Do not store in a bathroom.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.
- Do not use if seal over bottle opening is broken or missing. Do not remove from carton until required for use.
- Keep TRUVADA in its original container and keep the container tightly closed.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF TRUVADA

30 TRUVADA film-coated tablets are packed in a 75 ml, white, high density polyethylene bottle, with a white polypropylene, child-resistant cap and a high density polyethylene dessicant cannister or sachet with silica gel. Bottles are sealed with an aluminium induction seal.

TRUVADA bottles are labelled with self-adhesive labels and placed with a leaflet into cardboard unit cartons.

IDENTIFICATION OF TRUVADA

TRUVADA tablets are light blue, capsule-shaped, film-coated tablets, debossed with “GILEAD” on one side and plain on the other.

REGISTRATION NUMBER

41/20.2.8/0171

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION

Date of registration: 13 April 2007

Date of the most recent amendment to the patient information leaflet as approved by the Authority: 27 November 2015

ZA_TRUVTAB_1511_01