PACKAGE LEAFLET
LEBANON

PACKAGE LEAFLET: INFORMATION FOR THE USER

Truvada 200 mg/245 mg film-coated tablets
Emtricitabine/tenofovir disoproxil

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT TRUVADA IS AND WHAT IT IS USED FOR

Truvada is a treatment for Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and over.

Truvada contains two active substances, *emtricitabine* and *tenofovir disoproxil*. Both of these active substances are *antiretroviral* medicines which are used to treat HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor* and tenofovir is a *nucleotide reverse transcriptase inhibitor*. However, both are generally known as NRTIs and they work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself. Truvada should always be used combined with other medicines to treat HIV infection. Truvada can be administered in place of emtricitabine and tenofovir disoproxil used separately at the same doses.

This medicine is not a cure for HIV infection. While taking Truvada you may still develop infections or other illnesses associated with HIV infection. You can also pass on the virus to others, so it is important to take precautions to avoid infecting other people.

2. BEFORE YOU TAKE TRUVADA

Do not take Truvada

- **If you are allergic** *(hypersensitive)* to emtricitabine, tenofovir, tenofovir disoproxil fumarate, or any of the other ingredients of Truvada listed at the end of this leaflet.

  If this applies to you, tell your doctor immediately.

Take special care with Truvada

- **Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys.** Truvada may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function. Your doctor may also order blood tests during treatment to monitor your kidneys and may advise you to take the tablets less often. Truvada is not recommended if you have severe kidney disease or are receiving haemodialysis.

Truvada is not usually taken with other medicines that can damage your kidneys (see *Taking other medicines*). If this is unavoidable, your doctor will monitor your kidney function once a week.

- **Talk to your doctor if you are over 65.** Truvada has not been studied in patients over 65 years of age. If you are older than this and are prescribed Truvada, your doctor will monitor you carefully.

- **Truvada is not for use in children and adolescents under 18 years of age.**

- **Talk to your doctor if you have a history of liver disease, including hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. Both active substances in Truvada show some activity against hepatitis B virus although emtricitabine is not approved for the treatment of hepatitis B infection. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests in order to carefully monitor liver function.

- **Once you start taking Truvada, look out for possible signs of lactic acidosis.** Medicines containing nucleoside analogues, including Truvada, can cause lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver. Deep, rapid breathing, drowsiness, and non specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of lactic acidosis. This rare but serious side effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight. If you have liver disease you may also be more at risk of getting this condition. While you are being treated with Truvada, your doctor will monitor you closely for any signs that you may be developing lactic acidosis.

Other precautions

Combination antiretroviral therapies (including Truvada) may raise blood sugar, increase blood fats (hyperlipaemia), cause changes to body fat, and resistance to insulin (see section 4, *Possible side effects*).

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

Look out for infections. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with Truvada is started. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking Truvada. If you notice signs of inflammation or infection, **tell your doctor at once.**

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Bone problems. Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the

hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms inform your doctor.

Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 4, *Possible side effects*).

Taking other medicines

You should not take Truvada if you are already taking other medicines that contain the components of Truvada, emtricitabine and tenofovir disoproxil fumarate, or any other antiviral medicines that contain lamivudine or adefovir dipivoxil.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- **It is especially important to tell your doctor if you are taking other medicines which may damage your kidneys.**
  These include:

  - aminoglycosides (for bacterial infection)
  - amphotericin B (for fungal infection)
  - foscarnet (for viral infection)
  - ganciclovir (for viral infection)
  - pentamidine (for infections)
  - vancomycin (for bacterial infection)
  - interleukin-2 (to treat cancer)
  - cidofovir (for viral infection)

- **Other medicines containing didanosine (for HIV infection):** Taking Truvada with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes causes death, have been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

Do not stop your treatment without contacting your doctor.

Taking Truvada with food and drink

- **Truvada should be taken with food.**

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

- **You must not take Truvada during pregnancy** unless specifically discussed with your doctor. Although there are limited clinical data on the use of Truvada in pregnant women, it is not usually used unless absolutely necessary.

- If you are a woman who could get pregnant during treatment with Truvada, you must use an effective method of contraception to avoid becoming pregnant.

- If you become pregnant, or plan to become pregnant, ask your doctor about the potential benefits and risks of therapy with Truvada to you and your child.

If you have taken Truvada during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

- **Do not breast-feed during treatment with Truvada.** This is because the active substances in this medicine pass into human breast milk.

- If you are a woman with HIV it is recommended that you do not breast-feed, to avoid passing the virus to the baby in breast milk.

Driving and using machines

Truvada can cause dizziness. If you feel dizzy while taking Truvada, **do not drive** and do not use any tools or machines.

Important information about some of the ingredients of Truvada

Tell your doctor if you are lactose-intolerant or intolerant to other sugars. Truvada contains lactose monohydrate. If you know you are lactose-intolerant, or if you have been told that you have an intolerance to any other sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE TRUVADA

- **Always take Truvada exactly as your doctor has told you.** You should check with your doctor or pharmacist if you are not sure.

The usual dose:

- **Adults: one tablet each day with food.**

If you have difficulty swallowing, you can use the tip of a spoon to crush the tablet. Then mix the powder with about 100 ml (half a glass) of water, orange juice or grape juice, and drink immediately.

- **Always take the dose recommended by your doctor.** This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

- **If you have problems with your kidneys,** your doctor may advise you to take Truvada less frequently.

- **If your doctor decides to stop** one of the components of Truvada or change the dose of Truvada, you may be given emtricitabine and/or tenofovir separately instead of the combined medicine or other medicines for the treatment of HIV infection.

- **Your doctor will prescribe Truvada with other antiretroviral medicines.** Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

If you take more Truvada than you should

If you accidentally take more than the recommended dose of Truvada, contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Truvada

It is important not to miss a dose of Truvada.

If you do miss a dose of Truvada within 12 hours of when it is usually taken, take it as soon as you can, and then take your next dose at its regular time.

If it is almost time (less than 12 hours) for your next dose anyway, forget about the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you throw up less than 1 hour after taking Truvada, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Truvada.

If you stop taking Truvada

- **Stopping treatment** with Truvada may reduce the effectiveness of the anti-HIV therapy recommended by your doctor. Speak with your doctor before you stop taking Truvada for any reason, particularly if you are experiencing any side effects or you have another illness. Contact your doctor before you restart taking Truvada tablets.

- **If you have HIV infection and hepatitis B,** it is especially important not to stop your Truvada treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Truvada. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis.

  Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Truvada can cause side effects, although not everybody gets them.

Tell your doctor about any of the following side effects:

Very common side effects
(These can affect at least 10 in every 100 patients treated)

- diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness, headache, rash
- feeling weak, weakness (if creatine kinase levels in the blood are increased)

Tests may also show:
- decreases in phosphate in the blood

Common side effects
(These can affect 1 to 10 in every 100 patients treated)

- pain, stomach pain
- 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, such as wheezing, swelling or feeling light-headed

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
- liver and pancreas problems

Uncommon side effects
(These can affect at least 1 in every 1,000 patients treated, but less than 1 in every 100 patients treated)

- anaemia (low red blood cell count)
- pain in the abdomen (tummy) caused by inflammation of the pancreas
- breakdown of muscle, muscle pain or weakness
- swelling of the face, lips, tongue or throat

Tests may also show:
- decreases in potassium in the blood
- increased creatinine in your blood
- changes to your urine

Rare side effects
(These can affect at least 1 in every 10,000 patients treated, but less than 1 in every 1,000 patients treated)

- **lactic acidosis (excess lactic acid in the blood)** is a serious side effect that can be life-threatening. The following side effects may be signs of lactic acidosis:
  - deep rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting) and stomach pain

  If you think you may have lactic acidosis, contact your doctor immediately.

- back pain caused by kidney problems, including kidney failure. Your doctor may do blood tests to see if your kidneys are working properly.
- fatty liver
- yellow skin or eyes, itching, or pain in the abdomen (tummy) caused by inflammation of the liver
- inflammation of the kidney, passing a lot of urine and feeling thirsty
- softening of the bones (with bone pain and sometimes resulting in fractures)

Tests may also show:
- damage to kidney tubule cells

The breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.

Other possible effects

Children who were administered emtricitabine, one of the components of Truvada, also experienced anaemia (low red blood cell count), commonly and changes in skin colour including darkening of the

skin in patches, very commonly. If the production of red blood cells is reduced, a child may have symptoms of tiredness or breathlessness.

Truvada may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face; gain fat around the abdomen (tummy) and internal organs; get larger breasts or fatty lumps on the back of the neck ('buffalo hump'). The cause and the long-term effects of these changes are not yet known.

Truvada may also cause hyperlipaemia (increased fats in the blood) and resistance to insulin. Your doctor will test for these changes.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TRUVADA

Keep out of the reach and sight of children.

Do not use Truvada after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Store below 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Truvada contains

- **The active substances are** *emtricitabine* and *tenofovir disoproxil*. Each Truvada film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300 mg of tenofovir disoproxil fumarate or 136 mg of tenofovir).

- **The other ingredients are** croscarmellose sodium, glycerol triacetate (E1518), hypromellose (E464), indigo carmine aluminium lake (E132), lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), pregelatinised starch (gluten free) and titanium dioxide (E171).

What Truvada looks like and contents of the pack

Truvada film-coated tablets are blue, capsule-shaped tablets, engraved on one side with the word "GILEAD" and on the other side with the number "701". Truvada comes in bottles of 30 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

The following pack size is available: outer carton containing 1 x 30 film-coated tablet bottle. .

Marketing Authorisation Holder and Manufacturer

Gilead Sciences International Ltd
Cambridge
CB21 6GT
United Kingdom

Manufacturer:
Gilead Sciences Limited
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

To report any side effect(s):

Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of each of children.

Council of Arab Health Ministers and Union of Arab Pharmacists

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