

## **B. PACKAGE LEAFLET**

## Package leaflet: information for the user

### Truvada 200 mg / 245 mg film-coated tablets

Emtricitabine / tenofovir disoproxil

**Read all of this leaflet carefully before taking this medicine as 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See paragraph 4.

#### Contents of this leaflet:

1. What Truvada is and what it is used for
2. What you need to know before you take Truvada
3. How to take Truvada
4. Possible side effects
5. How to store Truvada
6. Contents of the pack and other information

#### 1. What Truvada is and what it is used for

**Truvada contains two active ingredients, *emtricitabine* is *tenofovir disoproxil*.** Both active ingredients are medicinal *antiretrovirals* which are used to treat HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor* and tenofovir is a *nucleotide reverse transcriptase inhibitor*. However, they are generically known as NRTIs and work by interfering with the normal activity of an enzyme (reverse transcriptase) which is essential for the virus to reproduce.

- **Truvada is used to treat human immunodeficiency virus 1 (HIV-1) infection, in adults**
- **It is also used to treat HIV in adolescents aged 12 to 18 years who weigh at least 35 kg** and who have already been treated with other HIV medicines that are no longer effective or have caused side effects.

- Truvada must always be used in combination with other medicines to treat HIV infection.
- Truvada can be given as a replacement for emtricitabine and tenofovir disoproxil used separately at the same doses.

**HIV positive people can transmit HIV** even when taking this medicine, although the risk is reduced by effective antiviral therapy. Discuss with your doctor the necessary precautions to avoid passing the infection to other people.

**This medicine is not a cure for HIV infection.** You may still develop infections or other illnesses associated with HIV infection while taking Truvada.

- **Truvada is also used to reduce the risk of getting HIV-1 infection in adults and adolescents aged 12 to less than 18 years weighing at least 35 kg.** when taken daily, along with safe sexual practices:

See section 2 for a list of precautions to be taken against HIV infection.

## 2. What you need to know before you take Truvada

**Do not take Truvada to treat HIV or to reduce the risk of getting HIV if you are allergic** to emtricitabine, tenofovir, tenofovir disoproxil or any of the other ingredients of this medicine (listed in section 6).

- **If this applies to you, tell your doctor immediately.**

### Before taking Truvada to reduce the risk of getting HIV:

Truvada can only help reduce the risk of getting HIV **before** that you are infected.

- **To start taking Truvada to reduce the risk of getting HIV you must be HIV negative.** She needs to get tested to make sure she doesn't already have an HIV infection. Do not take Truvada to reduce your risk unless you have been confirmed to be HIV negative. People who have HIV must take Truvada in combination with other medicines.
- **Many HIV tests may not detect a recent infection.** If he catches a flu-like illness, it could mean he was recently infected with HIV. These can be signs of HIV infection:
  - fatigue
  - temperature
  - joint or muscle pain headache
  - 
  - vomiting or diarrhea
  - rash
  - night sweats
  - swollen lymph nodes in the neck or groin
  - **Tell your doctor if you have a flu-like illness**, in the month before starting Truvada or at any time while taking Truvada.

### Warnings and Precautions

#### While taking Truvada to reduce the risk of getting HIV:

- Take Truvada every day **to reduce your risk, not just when you think you were at risk of getting an HIV infection.** Do not miss any dose of Truvada and do not stop taking it. Skipping doses can increase the risk of getting HIV infection.
- Get tested for HIV regularly.
- If you think you are infected with HIV, tell your doctor right away. He may have other tests on her to make sure she's still HIV-negative.
- **Simply taking Truvada may not stop you from contracting HIV.**
  - or Always practice safe sex. Use condoms to reduce contact with semen, vaginal fluid, or blood.
  - or Do not share personal items that may have blood or body fluids on them, such as toothbrushes or razor blades.
  - or Do not share or reuse needles or other injection or drug delivery equipment.
  - or Get tested for other sexually transmitted infections such as syphilis and gonorrhea. These infections facilitate HIV infection.

Ask your doctor if you have any other questions about how not to get HIV or how not to spread HIV to other people.

**While taking Truvada to treat HIV or to reduce the risk of getting HIV:**

- **Truvada can affect the kidneys.** Before and during treatment, your doctor may order blood tests to measure correct kidney function. Tell your doctor if you have had kidney disease, or if tests have shown kidney problems. Truvada should not be given to adolescents with kidney problems. If you have kidney problems, your doctor may advise you to stop taking Truvada or, if you already have HIV, to take Truvada less frequently. Truvada is not recommended if you have severe kidney disease or are on dialysis.

Bone problems (sometimes resulting in fractures) can also occur due to damage to the tubular cells of the kidneys (see section 4, *Possible side effects*).

- **Tell your doctor if you have ever had liver problems, including hepatitis.** HIV-infected patients who also have liver problems (including chronic hepatitis B or C) who are treated with antiretrovirals have a higher risk of severe and life-threatening liver complications. If you have hepatitis B or C, your doctor will carefully consider the best treatment regimen for you.
- **Find out if you are infected with the hepatitis B virus (HBV)** before you start taking Truvada. If you have an HBV infection, there is a serious risk of liver problems if you stop taking Truvada, whether you have HIV or not. It is important that you do not stop taking Truvada without talking to your doctor: see section 3, *Do not stop taking Truvada*.
- **Tell your doctor if you are over 65.** Truvada has not been studied in patients over 65 years of age.
- **Tell your doctor if you are lactose intolerant** ( see Truvada contains lactose later in this section).

**Children and adolescents**

Truvada is not indicated for children under 12 years of age.

**Other medicines and Truvada**

**Do not take Truvada** if you are already taking other medicines that contain the components of Truvada (emtricitabine and tenofovir disoproxil) or any other antiviral medicines that contain tenofovir alafenamide, lamivudine or adefovir dipivoxil.

**Taking Truvada with other medicines that can damage your kidneys:** it is especially important to tell your doctor if you are taking any of these medicines, including

- 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 (for cancer treatment) cidofovir (for viral infection)
- non-steroidal anti-inflammatory drugs (NSAIDs, used to relieve bone or muscle pain)

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your doctor may order blood tests to better check your kidney function.

**It is also important to warn your doctor** if you are taking ledipasvir / sofosbuvir, sofosbuvir / velpatasvir or sofosbuvir / velpatasvir / voxilaprevir to treat a hepatitis C infection.

**Taking Truvada with other medicines that contain didanosine (for the treatment of HIV infection):** Taking Truvada with other antiviral medicines that contain didanosine may increase the level of didanosine in your blood and may reduce CD4 cell counts. Inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), sometimes leading to death, have been reported rarely when medicines containing tenofovir disoproxil and didanosine were taken together. Your doctor will need to carefully consider whether to treat you with tenofovir and didanosine in combination.

- **Tell your doctor** if you are taking any of these medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

#### **Truvada with food and drink**

- Whenever possible, Truvada should be taken with food.

#### **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Although there are limited clinical data on the use of Truvada in pregnant women, it is generally not used unless strictly necessary.
- If you are pregnant or planning to become pregnant, ask your doctor about the potential benefits and risks of Truvada therapy for you and your baby.

If you have already taken Truvada during your pregnancy, your doctor may regularly order blood tests and other diagnostic tests to monitor the baby's development. In children whose mothers took NRTIs during pregnancy, the benefit of HIV protection outweighed the risk of side effects.

- **Do not breast-feed while taking Truvada.** The reason is that the active ingredient of this medicine is excreted in breast milk.
- If you are an HIV-infected woman, it is recommended that you do not breast-feed, to avoid passing the HIV virus to the baby through milk.

#### **Driving and using machines**

Truvada can cause dizziness. If you feel dizzy while taking Truvada, **you don't drive** and do not use tools or machinery.

#### **Truvada contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. How to take Truvada

- **Always take this medicine exactly as your doctor has told you.** If in doubt, consult your doctor or pharmacist.

#### The recommended dose of Truvada to treat HIV is:

- **Adults:** one tablet each day, when possible taken with food.
- **Adolescents between the ages of 12 and 18 weighing at least 35 kg:** one tablet each day, when possible taken with food.

#### The recommended dose of Truvada to reduce the risk of getting HIV is:

- **Adults:** one tablet each day, when possible taken with food.
- **Adolescents aged 12 to less than 18 years weighing at least 35 kg:** one tablet each day, when possible taken with food.

If you have difficulty swallowing, you can use the end 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 medicines are fully effective and to reduce the risk of developing resistance to the treatment. Do not change your dose unless your doctor tells you to.
- **If you are being treated for HIV infection,** your doctor will prescribe Truvada with other antiretroviral medicines. Consult the package leaflets of the other antiretrovirals for guidance on taking these medicines.
- **If you are taking Truvada to reduce the risk of getting HIV,** take Truvada every day, not just when you think you may have been at risk of HIV infection.

Talk to your doctor if you have questions about how not to get HIV or how to prevent the spread of HIV to other people.

#### If you take more Truvada than you should

If you accidentally take more Truvada than recommended, contact your doctor or the nearest emergency center. Take the bottle of tablets with you so that you can easily describe what you have taken.

#### If you miss a dose

It is important not to skip the doses of Truvada.

- **If you notice within 12 hours** from the time you usually take Truvada, take the tablet, preferably with food, as soon as possible. Then take your next dose at the scheduled time.
- **If he notices it 12 hours or more later** your usual time of taking Truvada, do not take the missed dose. Wait and take your next dose, preferably with food, at the scheduled time.

**If vomiting occurs within 1 hour of taking Truvada,** take another tablet. You should not take another tablet if you have vomited more than an hour after taking Truvada.

## Do not stop taking Truvada

- **If you are taking Truvada to treat HIV infection**, stopping the tablets may reduce the effectiveness of the anti-HIV therapy recommended by your doctor.
- **If you take Truvada to reduce the risk of getting HIV**, do not stop taking Truvada and do not skip the doses. If you stop using Truvada, or miss a dose, the risk of getting HIV infection may increase.
- **Do not stop taking Truvada without contacting your doctor.**
- **If you have hepatitis B**, It is especially important not to stop taking Truvada without first contacting your doctor. Blood tests may need to be repeated for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, discontinuation of treatment is not recommended as it can lead to worsening of hepatitis, which can be potentially fatal.
- **Tell your doctor immediately** any new or unusual symptoms seen after stopping treatment, especially symptoms that are normally associated with hepatitis B infection.

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

## 4. Possible side effects

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

### Possible serious side effects:

- **Lactic acidosis** ( excess lactic acid in the blood) is a rare side effect that can be fatal. Lactic acidosis occurs more often in women, especially if they are overweight, and in people with liver disease. The following can be signs of lactic acidosis:
  - wheezing
  - drowsiness
  - feeling of nausea, vomiting,
  - stomach pain
- **If you think you have lactic acidosis, contact a doctor immediately.**
- **Any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation due to infections may occur soon after starting HIV treatment previous. These symptoms are believed to be due to an improvement in the body's immune response, which allows the body to fight infections that may have been present without obvious symptoms.
- **Autoimmune Disorders**, in which the immune system attacks healthy body tissue, they can also occur after you start taking medicines to treat HIV infection. Autoimmune disorders can occur many months after starting treatment. Look for any symptoms of infection or other symptoms such as:
  - muscle weakness
  - weakness starting in the hands and feet and moving up to the trunk palpitations,
  - tremor or hyperactivity

- If you notice these or any other symptoms of inflammation or infection, seek immediate medical attention.

#### **Possible side effects:**

##### **Very common side effects**

*( can occur in more than 1 patient in every 10 patients)*

- diarrhea, vomiting, nausea
- dizziness, headache
- rash
- sense of weakness, muscle weakness

*Analyzes can also show:*

- reductions in blood phosphate creatine
- kinase elevated

##### **Common side effects**

*( can occur in a maximum of 1 patient in every 10 patients)*

- pain, stomach pain
- difficulty sleeping, nightmares
- digestive problems resulting from being unwell after meals, feeling full, gas, rash (including red spots or pustules sometimes with blistering and swelling of the skin), which may be an allergic reaction, burning, change in skin color with the onset of patches dark.
- other allergic reactions, such as wheezing, bloating or light-headedness

*Analyzes can also show:*

- decrease in white blood cell count (this can make you more prone to infection) increase in triglycerides (fatty acids), bile or glucose in the blood
- liver and pancreas problems

##### **Uncommon side effects**

*( can occur in a maximum of 1 patient in 100 patients)*

- abdominal pain caused by inflammation of the pancreas swelling of the
- face, lips, tongue or throat
- anemia (low red blood cell count)
- breakdown of muscles, muscle pain or muscle weakness, which can occur from damage to kidney tubule cells

*Analyzes can also show:*

- decreased potassium in the blood increased
- creatinine in the blood changes in urine
- 

##### **Rare side effects**

*( can occur in a maximum of 1 patient in 1,000 patients)*

- lactic acidosis (see *Possible serious side effects*)
- fat liver
- yellow skin and eyes, abdominal itching or pain caused by inflammation of the liver inflammation of the kidneys, large urine and thirst, kidney failure, damage to kidney tubular cells
- softening of the bones (with bone pain and sometimes fractures) back pain
- caused by kidney problems



Damage to kidney tubule cells can be associated with breakdown of muscles, softening of the bones (with bone pain and sometimes fractures), muscle pain, muscle weakness, and decreased potassium or phosphate in the blood.

- **If you notice any of the side effects listed above or if any of them become serious, ask your doctor or pharmacist.**

The frequency of the following side effects is unknown.

- **Bone problems.** Some patients taking combination antiretroviral medicines such as Truvada may develop a bone disease called *osteonecrosis* (bone death caused by loss of blood supply to bone). Taking this type of medicine for a long time, taking corticosteroids, alcohol, a very weak immune system and being overweight can be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
  - joint stiffness
  - joint pain (especially in the hip, knee and shoulder) difficulty moving
  -
- **If you notice any of these symptoms, please contact your doctor.**

An increase in weight and in blood lipid and glucose levels may occur during treatment for HIV. This is partly related to the recovery of health and lifestyle and in the case of blood lipids, sometimes to the HIV medicines themselves. Your doctor will check for these changes.

#### **Other effects in children**

- Children given emtricitabine very commonly experienced skin discoloration including
  - onset of dark patches on the skin
- Children commonly experienced low red blood cell counts (anemia)
  - this can cause the baby to feel tired or short of breath
- **If you notice any of these symptoms, please contact your doctor.**

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Truvada**

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

## 6. Contents of the pack and other information

### What Truvada contains

- **The active ingredients 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 excipients are** croscarmellose sodium, glycerol triacetate (E1518), hypromellose (E464), indigo carmine aluminum 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, debossed with the word "GILEAD" on one side and the number "701" on the other side. Truvada is supplied in bottles of 30 tablets. Each bottle contains silica gel as a desiccant, which must be kept in the bottle to protect the tablets. The silica gel is contained in a separate sachet or jar and should not be swallowed.

The following packs are available: outer pack containing 1 bottle of 30 film-coated tablets and 90 (3 bottles of 30) film-coated tablets. Not all pack sizes may be marketed.

#### Marketing Authorization Holder:

Gilead Sciences Ireland UC  
Carrigtohill  
County Cork, T45 DP77  
Ireland

#### Producer:

Gilead Sciences Ireland UC  
IDA Business & Technology Park  
Carrigtohill  
County Cork  
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder:

#### België / Belgique / Belgien

Gilead Sciences Belgium SPRL-BVBA Tél / Tel: +  
32 (0) 24 01 35 50

#### България

Gilead Sciences Ireland UC Тел.:  
+ 353 (0) 1 686 1888

#### Česká republika

Gilead Sciences sro  
Tel: + 420 (0) 910 871 986

#### Danmark

Gilead Sciences Sweden AB Tlf: +  
46 (0) 8 5057 1849

#### Lietuva

Gilead Sciences Poland Sp. z o.o. Tel: + 48  
22 262 8702

#### Luxembourg / Luxemburg

Gilead Sciences Belgium SPRL-BVBA Tél / Tel: +  
32 (0) 24 01 35 50

#### Magyarország

Gilead Sciences Ireland UC Tel: +  
353 (0) 1 686 1888

#### Malta

Gilead Sciences Ireland UC Tel: +  
353 (0) 1 686 1888

**Deutschland**

Gilead Sciences GmbH  
Tel: + 49 (0) 89 899890-0

**Eesti**

Gilead Sciences Poland Sp.z oo Tel: + 48  
22 262 8702

**Ελλάδα**

Gilead Sciences Ελλάς Μ.ΕΠΕ. Τηλ: +  
30 (0) 210 8930 100

**España**

Gilead Sciences, SL  
Tel: + 34 (0) 91 378 98 30

**France**

Gilead Sciences  
Tél: + 33 (0) 1 46 09 41 00

**Hrvatska**

Gilead Sciences Ireland UC Tel: +  
353 (0) 1 686 1888

**Ireland**

Gilead Sciences Ireland UC Tel: +  
353 (0) 214 825 999

**Ísland**

Gilead Sciences Sweden AB Sími: +  
46 (0) 8 5057 1849

**Italy**

Gilead Sciences Srl  
Tel: + 39 (0) 02 439201

**Κύπρος**

Gilead Sciences Ελλάς Μ.ΕΠΕ. Τηλ: +  
30 (0) 210 8930 100

**Latvija**

Gilead Sciences Poland Sp.z oo Tel: + 48  
22 262 8702

**Nederland**

Gilead Sciences Netherlands BV Tel: + 31  
(0) 20 718 36 98

**Norge**

Gilead Sciences Sweden AB Tlf: +  
46 (0) 8 5057 1849

**Österreich**

Gilead Sciences GesmbH  
Tel: + 43 (0) 1 260 830

**Polska**

Gilead Sciences Poland Sp.z oo Tel: + 48  
22 262 8702

**Portugal**

Gilead Sciences, Lda.  
Tel: + 351 (0) 21 7928790

**Romania**

Gilead Sciences Ireland UC Tel: +  
353 (0) 1 686 1888

**Slovenija**

Gilead Sciences Ireland UC Tel: +  
353 (0) 1 686 1888

**Slovenská republika**

Gilead Sciences Slovakia sro Tel: +  
421 (0) 232 121 210

**Suomi / Finland**

Gilead Sciences Sweden AB Puh / Tel:  
+ 46 (0) 8 5057 1849

**Sverige**

Gilead Sciences Sweden AB Tel: +  
46 (0) 8 5057 1849

**United Kingdom**

Gilead Sciences Ltd.  
Tel: + 44 (0) 8000 113 700

**This leaflet was last revised on.**

Detailed information on this medicinal product is available on the website of the European Medicines Agency:  
<http://www.ema.europa.eu>.