

## **SECTION 1 ADMINISTRATIVE PARTICULARS OF THE PRODUCT**

### **1.17 Summary Product Characteristics (SPC)**

#### **1.17.2 Patient Information Leaflet (for all products not subject to Medical Prescription)**

Patient information leaflet of Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200/300 mg is provided overleaf

# **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised).  
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

## Information for the patient

[HA551 trade name]<sup>1</sup>  
emtricitabine/tenofovir disoproxil fumarate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What [HA551 trade name] is and what it is used for
2. What you need to know before you take [HA551 trade name]
3. How to take [HA551 trade name]
4. Possible side effects
5. How to store [HA551 trade name]
6. Contents of the pack and other information

#### 1. What [HA551 trade name] is and what it is used for

[HA551 trade name] is a treatment for human immunodeficiency virus (HIV) infection in adults and adolescents over 10 years of age weighing more than 30 kg.

To prevent the virus from becoming resistant [HA551 trade name] should always be given in combination with at least one other antiretroviral medicine.

[HA551 trade name] can also be used to reduce the risk of getting HIV-1 infection in adults and adolescents weighing more than 35 kg who are not HIV infected (i.e. HIV-negative) and are at high risk of getting infected with HIV. This is called oral pre-exposure prophylaxis (PrEP).

It should be used in combination with safer sex practices (see section 2).

[HA551 trade name] contains the active substances *emtricitabine* and *tenofovir disoproxil*. Both of these are *antiretroviral* medicines for the treatment of HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor*. Tenofovir disoproxil is a *nucleotide reverse transcriptase inhibitor*. Both active substances work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself.

#### 2. What you need to know before you take [HA551 trade name]

##### Do not take [HA551 trade name]:

-if you are allergic (hypersensitive) to emtricitabine, tenofovir, tenofovir disoproxil or any of the other ingredients of [HA551 trade name] listed at the end of this leaflet.

If this applies to you, tell your healthcare provider immediately and don't take [HA551 trade name].

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<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

† Formerly Ranbaxy Laboratories Limited.

**Before taking [HA551 trade name] to reduce the risk of getting HIV:**

[HA551 trade name] can only help reduce your risk of getting HIV **before** you are infected.

- **You must be HIV negative before you start to take [HA551 trade name] to reduce the risk of getting HIV.** You must get tested to make sure that you do not already have HIV infection. Do not take [HA551 trade name] to reduce your risk unless you are confirmed to be HIV negative. People who do have HIV must take [HA551 trade name] in combination with other drugs.
  - **Many HIV tests can miss a recent infection.** If you get a flu-like illness, it could mean you have recently been infected with HIV. These may be signs of HIV infection:
    - tiredness
    - fever
    - joint or muscle aches
    - headache
    - vomiting or diarrhoea
    - rash
    - night sweats
    - enlarged lymph nodes in the neck or groin
- **Tell your healthcare provider about any flu-like illness** – either in the month before starting [HA551 trade name], or at any time while taking [HA551 trade name].

**Warnings and precautions**

Talk to your healthcare provider before taking [HA551 trade name].

**While taking [HA551 trade name] to reduce the risk of getting HIV:**

- Do not miss any doses of [HA551 trade name], or stop taking it. Missing doses may increase your risk of getting HIV infection.
- Get tested for HIV regularly.
- If you think you were infected with HIV, tell your healthcare provider straight away. More tests may be necessary to make sure you are still HIV negative.
  - **Just taking [HA551 trade name] may not stop you getting HIV.**
  - Always practise safer sex. Use condoms to reduce contact with semen, vaginal fluids, or blood.
  - Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
  - Do not share or re-use needles or other injection or drug equipment.
  - Get tested for other sexually transmitted infections such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you.

Ask your healthcare provider if you have any more questions about how to prevent getting HIV or spreading HIV to other people.

**While taking [HA551 trade name] to treat HIV or to reduce the risk of getting HIV:**

- **[HA551 trade name] may affect your kidneys.** Before and during treatment, your healthcare provider may order blood tests to measure kidney function. Tell your healthcare provider if you have had kidney disease, or if tests have shown kidney problems. If you have kidney problems, your healthcare provider may advise you to stop taking [HA551 trade name] or, if you already have HIV, to take [HA551 trade

name] less frequently. [HA551 trade name] is not recommended if you have severe kidney disease or are on dialysis.

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

- **Talk to your healthcare provider if you have a history of liver disease, including hepatitis.** Patients infected with HIV who also have 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 or C, your healthcare provider will carefully consider the best treatment regimen for you.
  - **Know your hepatitis B virus (HBV) infection status** before starting [HA551 trade name]. If you have HBV, there is a serious risk of liver problems when you stop taking [HA551 trade name], whether or not you also have HIV. It is important not to stop taking [HA551 trade name] without talking to your healthcare provider: see section 3, If you stop taking [HA551 trade name].
- **Talk to your healthcare provider if you are over 65.** Emtricitabine/tenofovir disoproxil has not been studied in patients over 65 years of age.
- **This medicine is not a cure for HIV infection.** While taking [HA551 trade name] you may still develop infections or other illnesses associated with HIV infection. You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your healthcare provider the precautions needed to avoid infecting other people.

### Children

[HA551 trade name] is not for use in children under 10 years of age.

### Other medicines and [HA551 trade name]

Tell your healthcare provider if you are taking any other medicines or have recently taken other medicines. Make sure you mention herbal medicines you might have been taking.

**Do not take** [HA551 trade name] if you are already taking other medicines that contain the components of [HA551 trade name] (emtricitabine and tenofovir disoproxil) or any other antiviral medicines that contain tenofovir alafenamide, lamivudine or adefovir dipivoxil.

**Taking [HA551 trade name] with other medicines that can damage your kidneys:** it is especially important to tell your healthcare provider 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 (to treat cancer)
- cidofovir (for viral infection)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve pain)

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your healthcare provider may order blood tests to closely monitor your kidney function.

**It is also important to tell your healthcare provider** if you are taking ledipasvir/sofosbuvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.

**Taking [HA551 trade name] with other medicines containing didanosine (for treatment of HIV infection):** Taking [HA551 trade name] 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 and didanosine were taken together. Your healthcare provider will carefully consider whether to treat you with combinations of tenofovir disoproxil and didanosine.

→ **Tell your healthcare provider** if you are taking any of these medicines. Tell your healthcare provider if you are taking, have recently taken or might take any other medicines.

#### **[HA551 trade name] with food and drink**

You can take [HA551 trade name] with food or between meals.

#### **Pregnancy and breast-feeding**

If you become pregnant or are planning to become pregnant, you must contact your healthcare provider to discuss the potential benefits and risks of taking this medicine to you and your child. Be sure to tell your healthcare provider immediately if you are or may be pregnant.

If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your healthcare provider.

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

[HA551 trade name] can cause dizziness. If you feel dizzy while taking [HA551 trade name], **do not drive** and do not use any hazardous tools or machines.

#### **[HA551 trade name] contains lactose**

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

### **3. How to take [HA551 trade name]**

Always take [HA551 trade name] exactly as your healthcare provider has told you. This is to make sure that your medicine is and remains fully effective. You should check with your healthcare provider if you are not sure. Do not change the dose unless your healthcare provider tells you to.

The dose for adolescents and adults is **one tablet each day**.

You can take [HA551 trade name] with food or between meals.  
Swallow [HA551 trade name] whole with water or another liquid.

When used for HIV-treatment:

This product is not for use by children under 10 years of age or adolescents weighing less than 30 kg.

When used for reducing the risk of getting HIV-1 infection:

This product is not for use by children under 10 years of age or adolescents weighing less than 35 kg.

For treatment of established HIV-infection:

Your healthcare provider will prescribe [HA551 trade name] with at least one other antiretroviral medicine. Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

If your healthcare provider decides to stop one of the components of [HA551 trade name] or change the dose of this medicine, you may be given emtricitabine and/or tenofovir disoproxil separately instead of the combined medicine or other medicines for the treatment of HIV infection.

If you have problems with your kidneys, your healthcare provider may advise you to take [HA551 trade name] less frequently.

**If you take more [HA551 trade name] than you should:**

If you accidentally take too many [HA551 trade name], contact your healthcare provider or nearest emergency department for advice. Take the tablet container with you so that you can easily describe what you have taken.

**If you forget to take [HA551 trade name]:**

It is important not to miss a dose of [HA551 trade name]. If you miss a dose of this medicine, take it as soon as you can, and then take your next dose at its regular time. However, if your next dose is due within 6 hours, do not take the missed dose. Wait and take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you vomit less than 1 hour after taking [HA551 trade name], take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking this medicine.

**If you stop taking [HA551 trade name]:**

Don't stop taking [HA551 trade name] without your healthcare provider's advice. Stopping [HA551 trade name] may reduce the effectiveness of the treatment. Talk to your healthcare provider before you stop taking [HA551 trade name] for any reason, particularly if you are experiencing any side effects, have another illness, or if you think you are no longer at risk of getting infected with HIV. Contact your healthcare provider before you restart taking [HA551 trade name].

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your [HA551 trade name] treatment without talking to your healthcare provider first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping this medicine. You may require blood tests for several months after stopping treatment. Tell your healthcare provider 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 healthcare provider.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects. Possible side effects of this medicine are listed below but they affect people differently and not everybody gets them.

The following side effects have been observed in patients who were treated for HIV-1 infection.

**Possible serious side effects:**

- **Lactic acidosis** (excess lactic acid in the blood) is a rare but potentially life-threatening side effect. Lactic acidosis occurs more often in women, particularly if they are overweight, and in people with liver disease. The following may be signs of lactic acidosis:
  - deep rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting)
  - stomach pain

**If you think you may have lactic acidosis, get medical help 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 from previous infections may occur soon after anti-HIV treatment is started. It is thought 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.

- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines to treat HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for 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

**If you notice these or any symptoms of inflammation or infection, get medical help immediately.**

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

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

*(may affect more than 1 in 10 people)*

- diarrhoea, being sick (vomiting), feeling sick (nausea)
- dizziness, headache
- rash
- feeling weak

*Tests may also show:*

- decreases in phosphate in the blood
- increased creatine kinase

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

*(may affect up to 1 in 10 people)*

- 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**

*(may affect up to 1 in 100 people)*

- pain in the abdomen (tummy) caused by inflammation of the pancreas
- swelling of the face, lips, tongue or throat
- anaemia (low red blood cell count)
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells

*Tests may also show:*

- decreases in potassium in the blood
- increased creatinine in your blood
- changes to your urine

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

*(may affect up to 1 in 1,000 people)*

- Lactic acidosis (see *Possible serious side effects*)
- 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, kidney failure, damage to kidney tubule cells
- softening of the bones (with bone pain and sometimes resulting in fractures)
- back pain caused by kidney problems

Damage to kidney tubule cells may be associated with 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.

- **If you notice any of the side effects listed above or if any of the side effects get serious**, talk to your healthcare provider.

The frequency of the following side effects is not known.

- **Bone problems.** Some patients taking combination of antiretroviral medicines such as [HA551 trade name] may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
  - joint stiffness
  - joint aches and pains (especially of the hip, knee and shoulder)
  - difficulty with movement

➤ **If you notice any of these symptoms tell your healthcare provider.**

During treatment for HIV there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your healthcare provider will test for these changes.

**Adults not infected with HIV and using tenofovir disoproxil/emtricitabine to reduce the risk of getting HIV-1 infection** did not experienced in clinical trials other side effects than those described above.

The following side effects were reported in at least 2% of the participants and occurred slightly more frequently in the treatment group (as compared to placebo):

Headache, abdominal pain, weight decrease and syphilis (a sexually transmitted infection).

### **Reporting of side effects**

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store [HA551 trade name]**

Do not store above 30°C, protect from moisture. Store in original container.

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

Do not use this medicine after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What [HA551 trade name] contains

The active ingredients are 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

The other ingredients are:

*Core tablet:* Microcrystalline cellulose, anhydrous lactose, pregelatinised starch, croscarmellose sodium and magnesium stearate.

*Film coat:* Hypromellose, lactose monohydrate, titanium dioxide and triacetin.

### What [HA551 trade name] looks like and contents of the pack

White to off-white, capsule-shaped film-coated tablets debossed with 'RF14' on one side and plain on the other side.

Pack types:

100cc HDPE Bottle Pack with CRC/Screw cap.

Pack size: 30s

200cc HDPE Bottle Pack with CRC/Screw cap

Pack size: 90s

### Supplier

Sun Pharmaceutical Industries Limited  
Sun House, 201 B/1  
Western Express Highway  
Goregaon (East)  
Mumbai – 400063, India

### Manufacturer

Sun Pharmaceutical Industries Limited  
Village Ganguwala,  
Paonta Sahib, District, Sirmour  
Himachal Pradesh 173025  
India

For any information about this medicine, contact the representatives of the supplier:

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*Detailed information on this medicine is available on the World Health Organization (WHO) web site:*  
<https://extranet.who.int/prequal/>.