

# Important Safety Information about Emtricitabine / Tenofovir disoproxil Accord to reduce the Risk of Getting Human Immunodeficiency Virus–1 (HIV-1) Infection

**This booklet is for adults taking Emtricitabine/ Tenofovir disoproxil  
Accord to reduce the risk of getting HIV-1 infection**

## **Emtricitabine/ Tenofovir disoproxil Accord to reduce the risk of getting HIV-1 Infection**

Emtricitabine/ Tenofovir disoproxil Accord is a prescription medicine to reduce the chance of getting HIV-1 infection in adults when used with safer sex practices. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Emtricitabine/ Tenofovir disoproxil Accord, to reduce the risk of getting HIV-1 infection, is meant for adults who are:

- HIV negative, and
- At high risk for getting HIV-1 infection through sex

Emtricitabine/ Tenofovir disoproxil Accord only works to reduce the risk of getting HIV-1 infection as part of a complete prevention strategy that includes safer sex practices and regular testing for HIV-1.

- Emtricitabine/ Tenofovir disoproxil Accord works better to reduce the risk of getting HIV-1 infection when the medicines are in your bloodstream *before* you are exposed to HIV-1
- You need to take Emtricitabine/ Tenofovir disoproxil Accord every day, not just when you think you have been exposed
- Just taking Emtricitabine/ Tenofovir disoproxil Accord alone may not keep you from getting HIV-1 infection

**accord**

**You must be HIV negative to start Emtricitabine/ Tenofovir disoproxil Accord. You must get tested to make sure that you do not already have HIV-1 infection. Do not take Emtricitabine/ Tenofovir disoproxil Accord to reduce the risk of getting HIV-1 infection unless you are confirmed to be HIV negative.**

**If you also have hepatitis B virus (HBV) infection and take Emtricitabine/ Tenofovir disoproxil Accord, your hepatitis B may become worse if you stop taking Emtricitabine/ Tenofovir disoproxil Accord.**

- Do not stop taking Emtricitabine/ Tenofovir disoproxil Accord without first talking with your healthcare provider
- If your healthcare provider stops Emtricitabine/ Tenofovir disoproxil Accord, your healthcare provider will need to watch you closely for several months to check your hepatitis B infection, or give you a medication to treat hepatitis B

Tell your healthcare provider about any new or unusual symptoms you have after you stop taking Emtricitabine/ Tenofovir disoproxil Accord.

## **What you should know before and while taking emtricitabine/ tenofovir disoproxil accord to reduce your risk of getting HIV infection**

**You must be HIV negative to start** Emtricitabine/ Tenofovir disoproxil Accord. Emtricitabine/ tenofovir disoproxil accord can only help reduce your risk of getting HIV before you are infected. You must get tested to make sure that you do not already have HIV. Do not take emtricitabine/ tenofovir disoproxil to reduce your risk unless you are confirmed to be HIV negative. Tell your healthcare provider if you had a flu-like illness within the last month before starting Emtricitabine/ Tenofovir disoproxil Accord or at any time while taking Emtricitabine/ Tenofovir disoproxil Accord. Symptoms of new HIV-1 infection include:

- Tiredness
- Fever
- Joint or muscle aches
- Headache
- Sore throat
- Vomiting or diarrhea
- Rash
- Night sweats
- Enlarged lymph nodes in the neck or groin

Take emtricitabine/ tenofovir disoproxil accord as prescribed. Do not miss any doses of emtricitabine/ tenofovir disoproxil accord, or stop taking it, unless directed by a healthcare professional. Missing doses and erratic intake of doses will increase your risk of getting HIV and to possibly developing resistance to the drug in case you get infected with HIV.

- Get tested for HIV regularly (e.g. at least every 3 months)
- If you think you were infected with HIV, tell your doctor right away. They may want to do more tests to be sure you are still HIV negative
- **Just taking emtricitabine/ tenofovir disoproxil accord may not stop you getting HIV. You must continue using safer sex practices** while you are taking emtricitabine/ tenofovir disoproxil to reduce your risk of getting HIV:
  - Use condoms to reduce contact with semen, vaginal fluids, or blood and avoid being exposed to other sexually transmitted infections
  - Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades
  - Do not share or reuse needles or other injection or drug equipment
- **Take action to stay negative while taking emtricitabine/ tenofovir disoproxil accord** for PrEP:
  - Get tested for other sexually transmitted infections, such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you
  - Get information and support to help reduce sexual behaviour that may put you at higher risk
- **Know your hepatitis B virus (HBV) infection status before starting emtricitabine/ tenofovir disoproxil accord:**
  - If you have HBV infection, there is a serious risk that liver problems may become worse after you stop taking emtricitabine/ tenofovir disoproxil accord

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

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. Your doctor may ask if you want to participate in a study (called the Antiretroviral Pregnancy Registry) which monitors the outcomes of women taking this medicine in pregnancy.

### **Always take emtricitabine/ tenofovir disoproxil accord exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.**

- The recommended dose is one emtricitabine/ tenofovir disoproxil accord tablet each day. Whenever possible, emtricitabine/ tenofovir disoproxil accord should be taken with food. Take emtricitabine/ tenofovir disoproxil accord every day, not just when you think you have been at risk of getting HIV infection
- Do not miss any doses of emtricitabine/ tenofovir disoproxil accord, or stop taking it unless told to by your doctor. Missing doses may increase your risk of getting HIV infection. If you miss a dose of emtricitabine/ tenofovir disoproxil accord and you notice:
  - Within 12 hours of the time you usually take emtricitabine/ tenofovir disoproxil accord, take the tablet, preferably with food as soon as possible. Then take the next dose at your usual time

- 12 hours or more after the time you usually take emtricitabine/ tenofovir disoproxil accord, forget about the missed dose. Wait and take the next dose, preferably with food, at your usual time
- If you vomit less than 1 hour after taking emtricitabine/ tenofovir disoproxil accord, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking emtricitabine/ tenofovir disoproxil accord

### **Side effects**

Like all medicines, emtricitabine/ tenofovir disoproxil can cause side effects, although not everybody gets them.

Read the patient information leaflet provided in the box containing your medicine for a full list of possible side effects.

Emtricitabine/ tenofovir disoproxil can cause serious side effects, including new or worsening of kidney problems and bone problems. Before and during treatment, your doctor may order blood tests to measure kidney function. Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys, or if you think you have any of the serious side effects listed in the patient information leaflet.

Very common side effects in people who take emtricitabine/ tenofovir disoproxil include: diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness, headache, rash and feeling weak.

Tell your doctor if you have any side effect that bothers you or does not go away. This includes any possible side effects not listed in the patient information leaflet.

## **How to store Emtricitabine/ Tenofovir disoproxil Accord**

- Store Emtricitabine/ Tenofovir disoproxil Accord at room temperature below 30°C
- Keep Emtricitabine/ Tenofovir disoproxil Accord in its original container and keep the container tightly closed
- Do not use Emtricitabine/ Tenofovir disoproxil Accord if seal over bottle opening is broken or missing

**Keep Emtricitabine/ Tenofovir disoproxil Accord and all other medicines out of reach of children.**

### **Reporting adverse events**

Suspected adverse reactions should be reported to the Health Products Regulatory Authority via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

Adverse reactions can also be reported to Accord Healthcare Ireland Ltd. via E-mail: [medinfo@accord-healthcare.com](mailto:medinfo@accord-healthcare.com); Tel: +44 (0) 1271 385 257; or by completing the online form at [www.accord-healthcare.ie/drug-reaction-report](http://www.accord-healthcare.ie/drug-reaction-report).

Further copies of the patients Guide may be obtained from Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork, T45 K857, Ireland; [www.accord-healthcare.ie/medical-information-form](http://www.accord-healthcare.ie/medical-information-form); Tel: (0)21 461 9040.