



## IMPORTANT INFORMATION

Important Information About Emtricitabine/Tenofovir disoproxil Clonmel to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection for individuals who have been prescribed Emtricitabine/Tenofovir disoproxil Clonmel for Pre-Exposure Prophylaxis (PrEP)

This guide is intended for information only and should complement (not replace) the patient information leaflet supplied with your medicine. For a full list of side effects and other important information, please refer to the patient information leaflet provided in the box containing your medicine. Ask your healthcare provider if you have any questions.

### What is Emtricitabine/Tenofovir disoproxil Clonmel for PrEP?

Emtricitabine/Tenofovir disoproxil Clonmel is used to reduce the risk of getting HIV-1 infection in adults, when used as a daily treatment, together with safer sex practices.

### What you should know before and while taking Emtricitabine/Tenofovir disoproxil Clonmel to reduce your risk of getting HIV infection

You must be HIV negative to start taking Emtricitabine/Tenofovir disoproxil Clonmel for PrEP. Emtricitabine/Tenofovir disoproxil Clonmel 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 Clonmel to reduce your risk unless you are confirmed to be HIV negative.**

Tell your doctor about any flu-like illness – either in the month before starting Emtricitabine/Tenofovir disoproxil Clonmel, or at any time while taking Emtricitabine/Tenofovir disoproxil Clonmel. If you get 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

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. Do not miss any doses of Emtricitabine/Tenofovir disoproxil Clonmel, or stop taking it without contacting your doctor. Missing doses may increase your risk of getting HIV infection.

- ▶ Know your HIV status and the HIV status of your partners.
- ▶ 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 Clonmel may not stop you getting HIV. You must continue using safer sex practices while you are taking Emtricitabine/Tenofovir disoproxil Clonmel 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 Clonmel 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 Clonmel:

If you have HBV infection, there is a serious risk that liver problems may become worse after you stop taking Emtricitabine/Tenofovir disoproxil Clonmel.

## How to take Emtricitabine/Tenofovir disoproxil Clonmel

Always take Emtricitabine/Tenofovir disoproxil Clonmel 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 Clonmel tablet each day. Whenever possible, Emtricitabine/Tenofovir disoproxil Clonmel should be taken with food. Take Emtricitabine/Tenofovir disoproxil Clonmel 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 Clonmel, 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 Clonmel and you notice:

- ▶ Within 12 hours of the time you usually take Emtricitabine/Tenofovir disoproxil Clonmel, 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 Clonmel, 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 Clonmel, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Emtricitabine/Tenofovir disoproxil Clonmel.



## 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.

## Possible side effects

Like all medicines, Emtricitabine/Tenofovir disoproxil Clonmel 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 Clonmel 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 kidney problems.

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

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet.

Any suspected adverse reactions to Emtricitabine/Tenofovir disoproxil Clonmel should be reported to Clonmel via email to [medicalinformation@clonmel-health.ie](mailto:medicalinformation@clonmel-health.ie) or by telephone to +353 52 6177777. You can also report side effects directly via the national reporting system: HPRa Pharmacovigilance, Earlsfort Terrace, Dublin, Ireland. Tel +353 1 6764971; Fax +353 1 6762517; Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie); Website: [www.hpra.ie](http://www.hpra.ie)

## How to store Emtricitabine/Tenofovir disoproxil Clonmel

- ▶ 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 bottle to protect from moisture. Keep the bottle tightly closed.

