

**Emtricitabine/Tenofovir disoproxil Mylan PrEP Educational guide for patient,
Global Version v. 1.1/01Nov2021**

This EM contains important safety information about Invented name (**Emtricitabine/Tenofovir disoproxil Mylan**) and advice on risk minimisation.

This booklet was developed by MAH.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to : Medicines Authority at <http://www.medicinesauthority.gov.mt/adrportal> Adverse reactions/events should also be reported to MAH at e-mail address and/or to the local representative of Viatrix : V.J. Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel:+356 21 220 174 and 24h PV mobile +356 99644126

Educational Guide for Individual to be prescribed PrEP

Important Information About Emtricitabine/Tenofovir disoproxil Mylan to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection for individuals who have been prescribed Emtricitabine/Tenofovir disoproxil 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 Mylan for PrEP?

Emtricitabine/Tenofovir disoproxil Mylan is a prescription medicine to help reduce the risk of getting HIV infection in adults and adolescents aged 12 years to less than 18 years who weigh at least 35 kg, when taken daily together with safer sex practices.

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

- **You must be HIV negative to start Emtricitabine/Tenofovir disoproxil Mylan for PrEP. Emtricitabine/Tenofovir disoproxil can only help reduce your risk of getting HIV before you are infected. You must**

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get tested to make sure that you do not already have HIV. Do not take Emtricitabine/ Tenofovir disoproxil Mylan 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 or at any time while taking Emtricitabine/ Tenofovir disoproxil. If you have engaged in sex practices that may put you at risk of getting 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.

Take Emtricitabine/Tenofovir disoproxil Mylan as prescribed by your doctor. Do not miss any doses of Emtricitabine/Tenofovir disoproxil Mylan or stop taking it. Missing doses and not taking the tablet as your doctor has told you to will increase your risk of getting HIV and may cause resistance to the drug in case you get infected with HIV.

- Get tested for HIV regularly (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 Mylan may not stop you getting HIV. You must continue using safer sex practices while you are taking Emtricitabine/Tenofovir disoproxil Mylan to reduce your risk of getting HIV:
 - o Use condoms to reduce contact with semen, vaginal fluids, or blood and avoid being exposed to other sexually transmitted infections.
 - o Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
 - o Do not share or reuse needles or other injection or drug equipment.

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- Take action to stay negative while taking Emtricitabine/Tenofovir disoproxil Mylan for PrEP:
 - o Get tested for other sexually transmitted infections, such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you
 - o 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 Mylan.

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

How to take Emtricitabine/Tenofovir disoproxil Mylan

Always take Emtricitabine/Tenofovir disoproxil Mylan exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose of Emtricitabine/Tenofovir disoproxil Mylan to reduce the risk of getting HIV is one Emtricitabine/Tenofovir disoproxil Mylan tablet each day. Take Emtricitabine/Tenofovir disoproxil Mylan every day, not just when you think you have been at risk of getting HIV infection. Whenever possible, Emtricitabine/Tenofovir disoproxil Mylan should be taken with food.
- To help you remember to take Emtricitabine/Tenofovir disoproxil Mylan you can add a reminder to your mobile phone or any other device that can alert you when it is time to take Emtricitabine/Tenofovir disoproxil Mylan
- Do not miss any doses of Emtricitabine/Tenofovir disoproxil Mylan 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 Mylan you notice:
 - o within 12 hours of the time you usually take Emtricitabine/Tenofovir disoproxil Mylan, take the tablet, preferably with food as soon as possible. Then take the next dose as usual.
 - o 12 hours or more after the time you usually take Emtricitabine/Tenofovir disoproxil Mylan, 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 Mylan, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Emtricitabine/Tenofovir disoproxil Mylan.

Side effects

Like all medicines, Emtricitabine/Tenofovir disoproxil Mylan 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 Mylan can cause serious side effects, including new or worse 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 Mylan 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.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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.

Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from moisture.