

EDUCATIONAL GUIDE FOR AT-RISK INDIVIDUALS ON PRE-EXPOSURE PROPHYLAXIS (PrEP)

Information for subjects who have been prescribed Emtricitabine/Tenofovir disoproxil as pre-exposure prophylaxis (PrEP).

This guide is for informational purposes only and should complement (not replace) the information in the package leaflet provided with your medicine. For the full list of side effects and other important information, see the package leaflet. Talk to your doctor if you have any questions.

What is Emtricitabine/Tenofovir disoproxil for PrEP?

Emtricitabine/Tenofovir disoproxil is a prescription medicine indicated to reduce the risk of contracting HIV-1 infection in adults and adolescents aged 12 to 18 years who

weigh at least 35 kg, when used as a daily treatment, together with safe sex practices.

What you should know before and during treatment with Emtricitabine/Tenofovir disoproxil to reduce risk to get HIV infection

- **You must be HIV negative before taking Emtricitabine/Tenofovir disoproxil for PrEP. This medicine may only help to reduce the risk of getting HIV infection before you are infected. You need to have a test to make sure you are not already infected with HIV. Do not take this medicine to reduce the risk of infection unless you have confirmation that you are negative for HIV.**
- Tell your doctor if you experience any flu-like symptoms, either within the month before you start taking Emtricitabine/Tenofovir disoproxil or at any time while you are taking this medicine. If you have been involved in sexual practices that may have put you at risk of becoming HIV, the following signs may be signs of HIV infection:
 - Tiredness or Fever
 - Muscle or joint pain
 - Headache or vomiting or diarrhoea
 - Rash or Night sweats
 - Enlarged lymph nodes in the neck or groin

Take Emtricitabine/Tenofovir disoproxil as directed by your doctor. Do not miss any dose or stop taking it. Missing the doses and not taking the pill as directed by your doctor will increase the risk of getting HIV and may cause the onset of resistance to the drug in case you become infected with HIV.

- Get tested for HIV regularly (e.g. at least every 3 months).
- If you think you have been infected with HIV, tell your doctor immediately. Your doctor may want to carry out further tests to make sure you are still negative for HIV.
- **Taking Emtricitabine/Tenofovir disoproxil alone may not prevent you from getting HIV.**
- **You should continue to adopt safe sex practices** to reduce the risk of contracting HIV: Use condoms to reduce contact with semen, vaginal fluids or blood and avoid being exposed to other sexually transmitted

diseases.

- Do not share personal items that may have blood or bodily fluids, such as toothbrushes and razors.
- Do not share or reuse needles or other injecting or drug-using utensils.
- **Take precautions to remain negative for HIV while using Emtricitabine/Tenofovir disoproxil for PrEP:**
- Be tested for other sexually transmitted infections, such as syphilis and gonorrhoea. These infections can facilitate infection by HIV.
- Get information and advice to help you reduce sexual behaviours that may put you at greater risk.
- **Know your hepatitis B virus (HBV) infection status before you start taking Emtricitabine/Tenofovir disoproxil.** If you have HBV infection, there is a high risk of severe liver inflammation when you stop taking the medicine.

How to take Emtricitabine/Tenofovir disoproxil

Take the medicine exactly as directed by your doctor. Talk to your doctor or pharmacist if you are not sure.

- The recommended dose is one tablet every day. Whenever possible, the drug should be taken with food.
- Take Emtricitabine/Tenofovir disoproxil every day, not just when you think you have been at risk of getting HIV infection.
- To help you remember to take this medicine, you can add a reminder on your mobile phone or any other device that alerts you when to take it.
- Do not miss any dose or stop taking Emtricitabine/Tenofovir disoproxil. Missing doses can increase the risk of getting HIV infection. If you miss a dose of medicine:
 - If you notice it up to 12 hours after your usual time of taking the medicine, take the tablet, preferably with food as soon as possible. Then, take the next dose as usual.
 - If you notice 12 hours or more after the time you usually take the medicine, do not take the missed dose. Wait and take the next dose, preferably with food, at

the usual time.

- If you vomit within 1 hour of taking it, take another tablet. You will not need to take another tablet if you have vomited more than 1 hour after taking this medicine.

Pregnancy and breastfeeding

If you are pregnant or nursing, think you may be pregnant, or plan to become pregnant, consult your doctor or pharmacist before taking this medicine. Your doctor may ask you if you want to take part in a study (called the *Antiretroviral Pregnancy Registry*) that monitors outcomes in women who take this medicine during pregnancy.

Undesirable effects

Like all medicines, Emtricitabine/Tenofovir disoproxil can cause side effects, although not everybody gets them. Read the package leaflet provided in the carton containing your medicine for the full list of possible side effects.

Emtricitabine/Tenofovir disoproxil can cause serious side effects, including the onset or worsening of kidney problems or bone problems.

Before and during treatment, your doctor may order blood tests to assess how well your kidneys are working. Tell your doctor if you have had kidney disease or if tests have shown changes in your kidneys, or if you think you have any of the serious side effects listed in the package leaflet.

Very common side effects in people taking this medicine include: diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness, headache, rash and weakness. Tell your doctor if you notice any side effects that bother you or do not go away, including possible side effects not listed in the package leaflet.

How to store Emtricitabine/Tenofovir disoproxil.

Keep the drug out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle/blister and carton after EXP. The expiry date corresponds to the last day of the month indicated.

You can find the approved storage conditions for your medicine on the carton or package leaflet.

Reporting of suspected undesirable effects

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 Generis : V.J. Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel:+356 21 220 174 and 24h PV mobile +356 99644126



