IMPORTANT INFORMATION ABOUT EMTRICITABINE/TENOFOVIR DISOPROXIL TO REDUCE THE RISK OF GETTING HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Information 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 for PrEP?

Emtricitabine/ tenofovir disoproxil is a prescription medicine to help reduce the risk of getting HIV infection, together with safer sex practices.

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

You must be HIV negative to start taking emtricitabine/ tenofovir disoproxil for PrEP.

Emtricitabine/ tenofovir disoproxil 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 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 as prescribed. Do not miss any doses of emtricitabine/ tenofovir disoproxil, 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 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 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:***

- If you have HBV infection, there is a serious risk that liver problems may become worse after you stop taking emtricitabine/ tenofovir disoproxil

How to take emtricitabine/ tenofovir disoproxil

Always take emtricitabine/ tenofovir disoproxil 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 tablet each day. Whenever possible, emtricitabine/ tenofovir disoproxil 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

• Do not miss any doses of emtricitabine/ tenofovir disoproxil, 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 and you notice:

– Within 12 hours of the time you usually take emtricitabine/ tenofovir disoproxil, 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, 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, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking emtricitabine/ tenofovir disoproxil

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.

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.

Reporting of side effects

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

Please continue to report suspected side effects to the MHRA through the Yellow Card Scheme.

Please report:

- *all suspected side effects that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason*
- *all suspected side effects associated with new drugs and vaccines identified by the black triangle▼*

It is easiest and quickest to report side effects online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary); by emailing yellowcard@mhra.gov.uk; at the back of the British National Formulary (BNF); by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789; or by downloading and printing a form from the Yellow Card website.