



## Important Information about Emtricitabine/Tenofovir disoproxil Krka to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection

### Information for individuals who have been prescribed Emtricitabine/Tenofovir disoproxil Krka for Pre-exposure prophylaxis (PrEP) (To be handed out by the prescriber)

*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 Krka for PrEP?

Emtricitabine/Tenofovir disoproxil Krka (emtricitabine/tenofovir disoproxil succinate) 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 35kg, when used as a daily treatment, together with safer sex practices.

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

**You must be HIV negative to start Emtricitabine/Tenofovir disoproxil Krka for PrEP. Emtricitabine/Tenofovir disoproxil Krka 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 Krka 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 Krka or at any time while taking Emtricitabine/Tenofovir disoproxil Krka. If you have engaged in sex practices that may put you at risk of getting HIV these may be signs of HIV infection:

- |                         |                        |  |
|-------------------------|------------------------|--|
| - tiredness             | - headache             | - night sweats                               |
| - fever                 | - vomiting or diarrhea | - enlarged lymph nodes in the neck or groin. |
| - joint or muscle aches | - rash                 |  |

**Take Emtricitabine/Tenofovir disoproxil Krka every day to reduce your risk of getting HIV, not just when you think you have been at risk.**

- Get tested for HIV regularly
- 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 Krka may not stop you getting HIV. You must continue using safer sex practices while you are taking Emtricitabine/Tenofovir disoproxil Krka to reduce your risk of getting HIV**
  - Always practice safer sex. Use condoms (except condoms made of lambskin) to reduce contact with semen, vaginal fluids, or blood.
  - 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 Krka for PrEP:**
  - Know your HIV status and the HIV status of your partners
  - Get tested for HIV regularly
  - Get tested for other sexually transmitted infections, such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you
  - Do not miss any doses of Emtricitabine/Tenofovir disoproxil Krka, or stop taking it. Missing doses may increase your risk of getting HIV
  - 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 Krka.** If you have HBV infection, there is a serious risk of acute liver inflammation when you stop taking Emtricitabine/Tenofovir disoproxil Krka

## How to take Emtricitabine/Tenofovir disoproxil Krka

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

- Take one Emtricitabine/Tenofovir disoproxil Krka tablet each day. Whenever possible, Emtricitabine/Tenofovir disoproxil Krka should be taken with food. Take Emtricitabine/Tenofovir disoproxil Krka 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 Krka, 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 Krka:
  - If you notice within 12 hours of the time you usually take Emtricitabine/Tenofovir disoproxil Krka, 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 Emtricitabine/Tenofovir disoproxil Krka, 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 Krka, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Emtricitabine/Tenofovir disoproxil Krka.

## 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.

## Side effects

**Like all medicines, Emtricitabine/Tenofovir disoproxil Krka 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 Krka can cause serious side effects, including new or worse kidney problems and bone problems. Tell your doctor immediately 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 Krka 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 Krka

- 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 package in order to protect from moisture. Keep the bottle tightly closed.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +3531 6764971; Fax: +3531 6762517. Website: [www.hpra.ie](http://www.hpra.ie); Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Any suspected adverse reactions can also be reported to Krka, d. d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto; Tel: +386 7 331 21 11 and +386 1 47 51 100; Website: [www.krka.si](http://www.krka.si); Email: [pharmacovigilance@krka.biz](mailto:pharmacovigilance@krka.biz).