Checklist for Prescribers

Initiation and follow up of Emtricitabine/Tenofovir disoproxil Krka for Pre-exposure Prophylaxis (PrEP)

Instructions: Complete checklist at each visit and file in individual's medical record.

I have completed the following prior to prescribing Emtricitabine/Tenofovir disoproxil Krka for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking Emtricitabine/Tenofovir disoproxil Krka for a PrEP indication:

Initial Evaluation

- ☐ Completed risk evaluation of uninfected individual
- ☐ Confirmed negative HIV-1 test immediately prior to initiating *Emtricitabine/Tenofovir disoproxil Krka for a PrEP indication*

  If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status; a combined antigen/antibody test should be used.
- ☐ Performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea
- ☐ If applicable, evaluated risk/benefit for women who may be pregnant or may want to become pregnant
- ☐ Performed HBV screening test
- ☐ Offered HBV vaccination as appropriate
- ☐ Prior to initiation confirmed estimated creatinine clearance (CrCl) is ≥60 mL/min

  Uninfected adults

  CrCl is ≥80 mL/min. If CrCl is <80 mL/min, use only if benefit outweighs risk. Not recommended if CrCl is <60mL/min.

  Uninfected adolescents

  Should not be used if CrCl <90mL/min/1.73m²
- ☐ Confirmed that the individual at risk is not taking other HIV-1 or HBV medications
- ☐ Confirmed that the individual at risk is not taking or has not recently taken a nephrotoxic medicinal product.

  If concomitant use of Emtricitabine/Tenofovir disoproxil Krka and nephrotoxic agents is unavoidable, renal function should be monitored weekly

Counselling

- ☐ Counselled on the importance of scheduled follow-up, including regular HIV-1 screening tests (e.g. at least every 3 months), while taking Emtricitabine/Tenofovir disoproxil Krka for a PrEP indication to reconfirm HIV-1-negative status
- ☐ Discussed the importance of discontinuing Emtricitabine/Tenofovir disoproxil Krka for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
- ☐ Counselled on the importance of adherence to daily dosing schedule
- ☐ Counselled that Emtricitabine/Tenofovir disoproxil Krka for a PrEP indication should be used only as part of a comprehensive prevention strategy and educated on practicing safer sex consistently and using condoms correctly
- ☐ Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)
- ☐ Discussed the importance of screening for sexually transmitted infections (STIs), such as syphilis and gonorrhoea, that can facilitate HIV-1 transmission
- ☐ Discussed known safety risks with use of Emtricitabine/Tenofovir disoproxil Krka for a PrEP indication
- ☐ Provided patient material to the individual at risk and reviewed this with them
- ☐ Recorded next follow up appointment and HIV-1 screening test dates in the Reminder card and handed this out to the individual
- ☐ Recommended to the individual to add a reminder to their mobile phone or any other device that can alert them when it is time to take Emtricitabine/Tenofovir disoproxil Krka

Follow up

- ☐ Performed regular HIV-1 screening (e.g. at least every 3 months)
- ☐ Checked the individual's reported adherence (e.g. from the calendar on the Reminder Card)
- ☐ Reassessed the individual at each visit to ascertain whether they remain at high risk of HIV-1 infection. The risk of HIV-1 infection should be balanced against the potential for renal and bone effects with long-term use of Emtricitabine/Tenofovir disoproxil Krka
- ☐ Discontinued Emtricitabine/Tenofovir disoproxil Krka for PrEP if seroconversion has occurred
- ☐ Performed screening for STIs, such as syphillus and gonorrhea
- ☐ Identified potential adverse reactions
- ☐ Performed renal monitoring as recommended

  In individuals without renal risk factors, renal function (creatinine clearance and serum phosphate) should be monitored after 2 to 4 weeks of use, after 3 months of use and every 3 to 6 months thereafter. In individuals at risk for renal impairment, more frequent monitoring of renal function is required

  Uninfected adults <u>and adolescents</u>

  Please refer to Safety leaflet for prescribers, section Emtricitabine/Tenofovir disoproxil Krka related renal toxicity
- ☐ Confirmed that CrCl is ≥60 mL/min and serum phosphate is ≥1.5 mg/dL (0.48 mmol/L)

  If creatinine clearance is decreased to <60 mL/min or serum phosphate is <1.5 mg/dL (0.48 mmol/L) in any individual receiving Emtricitabine/Tenofovir disoproxil Krka for PrEP, renal function should be re-evaluated within one week, including measurements of blood glucose, blood potassium and urine glucose concentrations. Consideration should also be given to interrupting treatment with Emtricitabine/Tenofovir disoproxil Krka in individuals with creatinine clearance decreased to <60 mL/min or decreases in serum phosphate to <1.0 mg/dL (0.32 mmol/L). Interrupting use of Emtricitabine/Tenofovir disoproxil Krka should also be considered in case of progressive decline of renal function when no other cause has been identified.
- ☐ Performed HBV screening test (if previously tested negative for HBV or had not received HBV vaccination)
- ☐ Recorded next follow-up appointment and HIV-1 screening test dates in the Reminder Card and provided this to the individual

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; Email: 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; Email: pharmacovigilance@krka.biz