Emtricitabine/Tenofovir disoproxil Checklist for Prescribers

Reporting of side effects
Healthcare providers are asked to report any suspected adverse reactions. This includes any possible side effects not listed in the patient information leaflet. You can report side effects directly via the national reporting system:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin
Tel: +353 1 6764971; Fax: +353 1 6762517
Website: www.hpra.ie ; e-mail: medsafety@hpra.ie

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

Patient Initials: _____ DOB: _____ Gender: M ☐ F ☐ Age: _____

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

Lab Tests/Evaluation

☐ Completed risk evaluation of uninfected individual

☐ Confirmed negative HIV-1 test immediately prior to initiating Emtricitabine/Tenofovir disoproxil 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 gonorrhoea

☐ 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)
• Emtricitabine/Tenofovir disoproxil is not recommended for use in HIV-1-uninfected individuals with CrCl <60 mL/min. Emtricitabine/Tenofovir disoproxil should only be used in individuals with CrCl <80 mL/min if the potential benefits are considered to outweigh the potential risks.

☐ Performed renal monitoring as recommended:

- in individuals without renal risk factors, renal function (CrCl 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

☐ 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 Mylan 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 for a PrEP indication to reconfirm HIV-1–negative status

☐ Discussed the importance of discontinuing Emtricitabine/Tenofovir disoproxil 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 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 for a PrEP indication to reconfirm HIV-1–negative status

☐ Discussed the importance of discontinuing Emtricitabine/Tenofovir disoproxil 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 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

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- ☐ 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 for a PrEP indication
- ☐ Reviewed the document 'Important Information About Emtricitabine/Tenofovir disoproxil to Reduce the Risk of Getting Human Immunodeficiency Virus (HIV) Infection' with the individual

Follow Up

- ☐ Recorded next follow up appointment and HIV-1 screening test dates in the Reminder card and handed this out to the individual
- ☐ Provided a copy of the document titled "Important Information About Emtricitabine/Tenofovir Disoproxil to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection" and the Patient Reminder Card to the individual
- ☐ 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)
- ☐ Discontinued emtricitabine/Tenofovir for PrEP if seroconversion has occurred
- ☐ Performed screening for STIs, such as syphilis and gonorrhoea
- ☐ Identified potential adverse reactions
- ☐ Performed renal monitoring as recommended

  • If CrCl is decreased to < 60 mL/min or serum phosphate is < 1.5 mg/dL (0.48 mmol/L) in any individual receiving Emtricitabine/Tenofovir for PrEP, renal function should be re-evaluated within 1 week, including measurements of blood glucose, blood potassium and urine glucose concentrations. Consideration should also be given to interrupting treatment with Emtricitabine/Tenofovir in individuals with CrCl decreased to < 60 mL/min or decreases in serum phosphate to < 1.0 mg/dL (0.32 mmol/L). Interrupting use of Emtricitabine/Tenofovir 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)

Reporter signature: _____ Print name: _____ Date: _____

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