Checklist for prescribers

Initiation of Emtricitabine/Tenofovir disoproxil Teva 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 Teva for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking Emtricitabine/Tenofovir disoproxil Teva 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 Teva for a PrEP indication using a combined antigen/antibody test. 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.
- ☐ 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 Teva is not recommended for use in HIV-1-uninfected individuals with CrCl < 60 mL/min. Emtricitabine/Tenofovir disoproxil Teva 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 disoproxil Teva 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 Teva for a PrEP indication to reconfirm HIV-1-negative status
- ☐ Discussed the importance of discontinuing Emtricitabine/Tenofovir disoproxil Teva for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
- ☐ Counselled on the importance of adherence to the dosing schedule
- ☐ Counselled that Emtricitabine/Tenofovir disoproxil Teva for a PrEP indication should be used only as part of a comprehensive prevention strategy and educated on practising 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 STIs, such as syphilis and gonorrhoea, that can facilitate HIV-1 transmission
- ☐ Discussed known safety risks with use of Emtricitabine/Tenofovir disoproxil Teva for a PrEP indication
- ☐ Reviewed the document *'Information for individuals who have been prescribed Emtricitabine/Tenofovir disoproxil Teva for Pre-Exposure Prophylaxis (PrEP)'* with the individual
- ☐ Provided a copy of the document titled *'Information for individuals who have been prescribed Emtricitabine/Tenofovir disoproxil Teva for Pre-Exposure Prophylaxis (PrEP)'* and the PrEP patient reminder card to the individual

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)
- ☐ Discontinued Emtricitabine/Tenofovir disoproxil Teva 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 disoproxil Teva 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 disoproxil Teva 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 disoproxil Teva 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

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Any suspected adverse reactions to Emtricitabine/Tenofovir disoproxil Teva should be reported to Teva via email to safety.ireland@teva.ie or by telephone to + 44 (0) 207 540 7117. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance, Earlsfort Terrace, Dublin, Ireland. Tel +353 1 6764971; Fax +353 1 6762517; Email: medsafety@hpra.ie; Website: www.hpra.ie