CHECKLIST FOR PRESCRIBERS

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

Emtricitabine/Tenofovir disoproxil Clonmel 200mg/245mg film-coated tablets Emtricitabine/Tenofovir disoproxil

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

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

Initial Evaluation

- ☐ Completed risk evaluation of uninfected individual
- ☐ Confirmed negative HIV-1 test immediately prior to initiating Emtricitabine/Tenofovir disoproxil Clonmel 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)
  Uninfected adults
  CrCl >80 mL/min. If CrCL <80 mL/min, use only if benefit outweighs risk. Not recommended if CrCl <60 mL/min.
- ☐ 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 Clonmel and nephrotoxic agents is unavoidable, renal function should be monitored weekly.

Counselling

- ☐ Counselled that Emtricitabine/Tenofovir disoproxil Clonmel 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
- ☐ Counselled on the importance of adherence to the dosing schedule
- ☐ 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 Clonmel
- ☐ Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)
- ☐ 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 Clonmel for a PrEP indication to reconfirm HIV-1-negative status
- ☐ Discussed the importance of discontinuing Emtricitabine/Tenofovir disoproxil Clonmel for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
- ☐ 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 Clonmel for a PrEP indication
- ☐ Provided patient material to the individual at risk and reviewed this with them.

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 Clonmel
- ☐ Discontinued Emtricitabine/Tenofovir disoproxil Clonmel for PrEP if seroconversion has occurred
- ☐ Performed screening for STIs, such as syphilis and gonorrhoea
- ☐ 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.
- ☐ 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

Any suspected adverse reactions to Emtricitabine/Tenofovir disoproxil Clonmel should be reported to Clonmel via email to medicalinformation@clonmel-health.ie or by telephone to +353 52 6177777. 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

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