

Prescriber Checklist

Initiation of ^{Pr}Mylan-Emtricitabine/Tenofovir Disoproxil for Pre exposure Prophylaxis (PrEP) in adults at high risk of HIV-1 infection

Instructions: Complete checklist at each visit and retain in patient's medical record.

I have completed the following prior to prescribing Mylan-Emtricitabine/Tenofovir Disoproxil for a pre-exposure prophylaxis (PrEP) indication (new or continuing prescription):

LAB TESTS / EVALUATION

- Determined whether patient qualifies as high risk for HIV-1 infection
- Confirmed a negative HIV-1 test immediately prior to initiating Mylan-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 or use a test approved by Health Canada as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection.
- Tested for the presence of hepatitis B virus (HBV) before initiating Mylan-Emtricitabine/Tenofovir Disoproxil
- Creatinine clearance calculated prior to initiation of therapy and/or periodically and confirmed (CrCl) to be above 60mL/min. Mylan-Emtricitabine/Tenofovir Disoproxil for a PrEP indication should not be used in HIV-1 uninfected individuals with creatinine clearance below 60 mL/min. In patients at risk of renal dysfunction, it is recommended that calculated creatinine clearance, serum phosphorus, urine glucose, and urine protein be assessed prior to initiation and periodically during Mylan-Emtricitabine/Tenofovir Disoproxil therapy.
- The patient is not taking other HIV-1 medications or HBV medications
- Completed risk/benefit analysis for women who may be pregnant or may want to become pregnant

COUNSELING / FOLLOW-UP

- Explained known safety risks and potential adverse reactions associated with use of Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP
- Explained that Mylan-Emtricitabine/Tenofovir Disoproxil should be part of a comprehensive prevention strategy, including safe sex practices, proper condom use, knowledge of one's HIV-1 status and of one's partner (if possible), and the testing for other sexually transmitted infections that can facilitate HIV-1 transmission, such as syphilis and gonorrhoea
- Explained the importance of discontinuing Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP if HIV-1 infection has occurred to reduce the development of resistant HIV-1 variants
- Counseled patient to strictly adhere to the recommended dosing schedule of Mylan-Emtricitabine/Tenofovir Disoproxil
- Explained the importance of HIV-1 screening tests at least once every 3 months while taking Mylan-Emtricitabine/Tenofovir Disoproxil for PrEP
- Reviewed the Mylan-Emtricitabine/Tenofovir Disoproxil Uninfected Patient Brochure with patient and explained where further information can be found

Mylan-Emtricitabine/Tenofovir Disoproxil is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.

Consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00048031.PDF for more information about conditions of clinical use, contraindications, warnings, precautions, adverse reactions, interactions and dosing. The Product Monograph is also available by calling 1 844 596-9526.