

EMTRICITABINA/TENOFOVIR DISOPROXIL

Instructions:

Complete a checklist at each doctor's appointment and file it with the individual's medical records.
Individual's Initials: _____

I checked each of the following points before prescribing Emtricitabine/Tenofovir disoproxil for the indication of pre-exposure prophylaxis (PrEP)

Laboratory Analysis/Evaluation

The risk assessment of the non-infected individual was completed

HIV-1 negative status was confirmed immediately prior to initiation of emtricitabine/tenofovir disoproxil for PrEP indication using a combined HIV-1 antigen/antibody test

• In the presence of clinical symptomatology consistent with acute viral infection and if recent exposure to HIV-1 (< 1 month) is suspected, pre-exposure prophylaxis should be postponed for at least one month and HIV-1 status should be reconfirmed

Screening tests for sexually transmitted infections (STIs), such as syphilis and gonorhea, were carried out

Benefit/risk assessed for women who may be pregnant or may want to become pregnant, if applicable

Hepatitis B virus (HBV) screening tests were carried out

HBV vaccine was proposed, if appropriate

It has been confirmed that the at-risk individual is not taking other medicines for HIV-1 or HBV

Creatinine clearance (CrCl) value was confirmed prior to initiation of therapy

Uninfected adults:

If CrCl < 80 ml/min, use this medicine only if the potential benefits outweigh the potential risks.

Not recommended if CrCl < 60 ml/min

Uninfected adolescents

Should not be used if CrCl < 90 ml/min/1.73m²

It has been confirmed that the high-risk individual is not taking, or has not recently taken, nephrotoxic medicines. If concomitant use of emtricitabine/tenofovir disoproxil and nephrotoxic agents is unavoidable, renal function should be monitored weekly

Advice

Advice was provided on the need to use emtricitabine/tenofovir disoproxil for PrEP only as part of an overall strategy for prevention of HIV-1 infection, including the use of other prevention measures such as consistent and correct condom use

Counselling was provided on the importance of complying with the daily dosing schedule

The recommendation was provided for the individual to add a reminder on their mobile phone or any other device that alerts them when it is time to take the medicine

The importance of the individual knowing their HIV status and, if possible, that of their partner was discussed

Counselling was provided on the importance of planning regular follow-up, including regular HIV-1 screening (e.g. at least every 3 months) while using Emtricitabine/Tenofovir disoproxil for PrEP to reconfirm HIV-1 negative status.

The importance of discontinuing the use of emtricitabine/tenofovir disoproxil for PrEP in the event of seroconversion was discussed to reduce the risk of developing resistant HIV-1 variants

The importance of screening for STIs, such as syphilis and gonorrhea, which can facilitate HIV-1 transmission, was discussed

The safety risks associated with the use of Emtricitabine/Tenofovir disoproxil for PrEP were discussed

The document "Educational Guide for Individuals at Risk on Pre-Exposure Prophylaxis (PrEP)" was provided and analyzed with the individual

Follow-up

Regularly tested for HIV-1 (e.g. every 3 months)

Checked adherence to the individual's reported therapy (e.g., from the calendar inserted in the "PrEP Card for At-Risk Individuals")

The individual is reassessed at each visit to see if they are still at high risk of HIV-1 infection. The risk of HIV-1 infection should be weighed against the potential renal and bone effects of long-term use of emtricitabine/tenofovir disoproxil

Discontinued Emtricitabine/Tenofovir disoproxil for PrEP if seroconversion occurs

Screening tests for STIs, such as syphilis and gonorrhea, performed

Potential adverse reactions identified

Kidney monitoring as recommended:

In subjects without renal risk factors, renal function (CrCl and serum phosphate) should be monitored after 2 to 4 weeks of therapy, after 3 months of therapy, and every 3 to 6 months thereafter. In individuals at risk for renal failure, closer monitoring of renal function is necessary.

Uninfected adults and adolescents

Please refer to the section "Emtricitabine/Tenofovir disoproxil-related renal toxicity" of the "Educational Guide for Prescribers on Pre-Exposure Prophylaxis (PrEP)"

HBV screening test (if previous test negative for HBV or if no HBV vaccination has occurred)

Recorded next follow-up appointment and HIV-1 testing dates on the PrEP At-Risk Card provided to the individual

Physician's Signature _____

Doctor's Name in Print _____

Date ____ / ____ / _____

