Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg for HIV-1 Pre-exposure Prophylaxis (PrEP)

Training Guide for Healthcare Providers

About emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg

INDICATION

Emtricitabine/tenofovir disoproxil fumarate is indicated in combination with safer sex practices for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg.* Individuals must have a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

- If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting HIV-1 PrEP for at least 1 month and reconfirm HIV-1 status or use a test cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection

PRESCRIBING CONSIDERATIONS: When prescribing emtricitabine/tenofovir disoproxil fumarate for pre-exposure prophylaxis:

- Only prescribe emtricitabine/tenofovir disoproxil fumarate as part of a comprehensive prevention strategy because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1
- Counsel all uninfected individuals to strictly adhere to their emtricitabine/tenofovir disoproxil fumarate daily dosing schedule because the effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 is strongly correlated with adherence and measurable drug levels

*Factors that may help to identify individuals at risk include individuals having partner(s) known to be HIV-1 infected or engaging in sexual activity within a high prevalence area or social network and one or more of the following: inconsistent or no condom use, diagnosis of sexually transmitted infections, exchange of sex for commodities (such as money, food, shelter, or drugs), use of illicit drugs or alcohol dependence, incarceration, or partner(s) of unknown HIV-1 status with any of the factors listed above.

- Confirm a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting HIV-1 PrEP for at least 1 month and reconfirm HIV-1 status or use a test cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection
- Screen uninfected individuals for HIV-1 infection at least once every 3 months while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Some individuals, such as adolescents, may benefit from more frequent visits and counseling
- Do not prescribe emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed

The following points should also be considered when prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in adolescents:

- Use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP as part of a comprehensive HIV prevention strategy for adolescents should include consideration of the ability of the individual to understand the importance of adherence to daily dosing, the need for frequent HIV testing, the need for frequent sexually transmitted infection testing, and the continued risk of pregnancy
- In a clinical study in adolescents, the percentage of subjects with protective levels of drug declined markedly after subjects switched from monthly to quarterly visits, suggesting that adolescents may benefit from more frequent visits and counseling

BOXED WARNING:

- **Emtricitabine/tenofovir disoproxil fumarate used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-1 negative immediately prior to initial use and periodically (at least every 3 months) during use. Drug-resistant HIV-1 variants have been identified with the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed**
- **Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued emtricitabine/tenofovir disoproxil fumarate. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in HBV-infected patients who discontinue emtricitabine/tenofovir disoproxil fumarate. If appropriate, initiation of anti–hepatitis B therapy may be warranted**

Why Use Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP?

By inhibiting HIV-1 from replicating as it enters the body, emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP works to prevent the virus from establishing permanent infection. However, emtricitabine/tenofovir disoproxil fumarate should not be seen as the first line of defense against HIV-1 infection. Because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection, emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP must be used in combination with a comprehensive prevention strategy that includes safer sex practices, such as regular and correct condom use, regular HIV-1 testing for themselves (and their sexual partner[s]), and other proven HIV-1 prevention methods to safely and effectively reduce the risk of acquiring HIV-1 infection.

- Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP must only be prescribed to uninfected individuals at risk who are confirmed to be HIV-1 negative
- Uninfected individuals who are prescribed emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should not miss any doses. Missing doses raises the risk of acquiring HIV-1 infection

Emtricitabine/tenofovir disoproxil fumarate is also indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Emtricitabine/tenofovir disoproxil fumarate should never be used alone in an individual infected with HIV-1 because of the increased risk of resistance. Therefore, it is critical to confirm negative HIV-1 status immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting HIV-1 PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. Screen for HIV-1 infection at least once every 3 months while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Some individuals, such as adolescents, may benefit from more frequent visits and counseling.

Key Findings of the Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP Trials

The iPrEx Trial

- In one clinical trial of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, emtricitabine/tenofovir disoproxil fumarate was shown to reduce the risk of HIV-1 infection acquisition by 42% for high-risk adult men who have sex with men who also received comprehensive prevention services, including monthly HIV-1 testing, condom provision, risk-reduction counseling, and management of other sexually transmitted infections
- In a post hoc case control study of plasma and intracellular drug levels in about 10% of clinical trial subjects, risk reduction appeared to be the greatest in subjects with detectable intracellular tenofovir. Efficacy was therefore strongly correlated with adherence
- Intensive risk reduction counseling was provided as part of the trial, and self-reported risk behavior among the subjects in this clinical trial declined overall during the trial, both in terms of decreases in the number of sexual partners and increases in condom use

The Partners PrEP Trial

- In another clinical trial of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in adult serodiscordant couples, emtricitabine/tenofovir disoproxil fumarate was shown to reduce HIV-1 infection acquisition by 75% for the uninfected individuals exposed to the virus through heterosexual sex
- In a post hoc case control study of plasma drug levels in about 10% of clinical trial subjects, risk reduction appeared to be the greatest in subjects with detectable plasma tenofovir. Efficacy was therefore strongly correlated with adherence

The ATN 113 Trial

- Safety, adherence, and resistance were evaluated in a single-arm, open-label clinical trial (ATN 113) in which 67 HIV-1 uninfected adolescent men who have sex with men received emtricitabine/tenofovir disoproxil fumarate once daily for HIV-1 PrEP
- In the ATN 113 trial, HIV-1 seroconversion occurred in three subjects. Tenofovir diphosphate (DP) levels in dried blood spot assays indicate that these subjects had poor adherence
- Adherence to study drug, as measured by tenofovir DP levels in dried blood spot assays, declined markedly after Week 12 once subjects switched from monthly to quarterly visits, suggesting that adolescents may benefit from more frequent visits and counseling

Emtricitabine/Tenofovir Disoproxil Fumarate Safety Profile

IMPORTANT SAFETY INFORMATION

Contraindications

- **Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is contraindicated in individuals with positive or unknown HIV-1 status**

Warnings and Precautions

Comprehensive Management to Reduce the Risk of Acquiring HIV-1 and Development of HIV-1 Resistance

Use emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP only as part of a comprehensive prevention strategy that includes other prevention measures, such as safer sex practices, because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1.

- Counsel uninfected individuals about safer sex practices, including:
  - Using condoms consistently and correctly
  - Knowing their HIV-1 status and that of their partner(s)
  - The importance of virologic suppression in their partner(s) with HIV-1
  - Being regularly tested for other sexually transmitted infections that can facilitate HIV-1 transmission (e.g., syphilis, chlamydia, and gonorrhea)
- Informing individuals about the importance of reducing sexually risky behaviors and supporting their efforts to do so
- **Use emtricitabine/tenofovir disoproxil fumarate to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-1 negative.** HIV resistance substitutions may emerge with individuals with undetected HIV-1 infection who are taking only emtricitabine/tenofovir disoproxil fumarate because emtricitabine/tenofovir disoproxil fumarate alone does not constitute a complete treatment regimen for HIV-1 infection. Therefore, care should be taken to minimize drug exposure in HIV-1 infected individuals:
  - Confirm a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
  - Many HIV-1 tests, such as rapid tests, detect anti-HIV antibodies and may not identify HIV-1 during the acute stage of infection. Prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, evaluate seronegative individuals for current or recent signs or symptoms consistent with acute viral infections (e.g., fever, fatigue, myalgia, skin rash) and ask about potential exposure events (e.g., unprotected, or condom broke during, sex with an HIV-1 infected partner) that may have occurred within the last month
  - If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting HIV-1 PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection
  - While using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, HIV-1 screening tests should be repeated at least every 3 months, and upon diagnosis of any sexually transmitted infections. Some individuals, such as adolescents, may benefit from more frequent visits and counseling
  - If a screening test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1, including acute or primary HIV-1 infection
- Counsel all uninfected individuals to strictly adhere to their emtricitabine/tenofovir disoproxil fumarate daily dosing schedule. The effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 is strongly correlated with adherence, as demonstrated by measurable drug levels in clinical trials
- **New onset or worsening renal impairment:**
  - Can include acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia)
  - Prior to initiating and during use of emtricitabine/tenofovir disoproxil fumarate, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance (CrCl), urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus
  - Emtricitabine/tenofovir disoproxil fumarate should be avoided with concurrent or recent use of a nephrotoxic agent (e.g., high-dose or multiple non-steroidal anti-inflammatory drugs [NSAIDS]). Cases of acute renal failure after initiation of high-doses or multiple NSAIDS have been reported. Some patients required hospitalization and renal replacement therapy. Alternatives to NSAIDS should be considered, if needed, in patients at risk for renal dysfunction

- **Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is not recommended in uninfected individuals with an estimated CrCl below 60 mL/min**
    - **If a decrease in estimated CrCl is observed while using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, evaluate potential causes and reassess potential risks and benefits of continued use**

- **HBV infection:**
    - All patients should be tested for chronic hepatitis B virus (HBV)
    - HBV-uninfected individuals should be offered vaccination
    - HBV-infected individuals should be monitored closely for exacerbations of hepatitis B for at least several months after discontinuing emtricitabine/tenofovir disoproxil fumarate (see **BOXED WARNING** above)

- **Lactic acidosis/severe hepatomegaly with steatosis:** Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Discontinue treatment in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity

- **Bone effects:**
    - Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia, have been seen in patients treated with tenofovir disoproxil fumarate. Consider assessment of BMD in individuals with a history of pathologic fracture or other risk factors for osteoporosis or bone loss
    - Persistent or worsening bone pain, pain in extremities, fractures, and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function in at-risk patients

- **Coadministration with other products:** Do not use emtricitabine/tenofovir disoproxil fumarate with drugs containing emtricitabine, tenofovir disoproxil fumarate, or tenofovir alafenamide, with drugs containing lamivudine, or with adefovir dipivoxil

Important Safety Information

Common Adverse Events

- In HIV-1 uninfected adults in PrEP trials, adverse reactions that were reported by more than 2% of emtricitabine/tenofovir disoproxil fumarate subjects and more frequently than by placebo subjects were headache, abdominal pain, and decreased weight

Important Safety Information About the Use of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP in Specific Populations

- **Pregnancy:**
    - Data on the use of emtricitabine/tenofovir disoproxil fumarate during pregnancy from observational studies have shown no increased risk of major birth defects
    - Published studies indicate an increased risk of HIV-1 infection during pregnancy and an increased risk of mother-to-child transmission during acute HIV-1 infection. In women at risk of acquiring HIV-1, consideration should be given to methods to prevent acquisition of HIV, including continuing or initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, during pregnancy
    - A pregnancy registry is available. Enroll pregnant women exposed to emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263

- **Lactation:**
  - It is not known if the components of emtricitabine/tenofovir disoproxil fumarate (emtricitabine and tenofovir disoproxil fumarate) affect milk production or have effects on the breastfed child
  - In HIV-1–uninfected women, the developmental and health benefits of breastfeeding and the mother's clinical need for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should be considered along with any potential adverse effects on the breastfed child from emtricitabine/tenofovir disoproxil fumarate and the risk of HIV-1 acquisition due to nonadherence and subsequent mother-to-child transmission
  - Women should not breastfeed if acute HIV-1 infection is suspected because of the risk of HIV-1 transmission to the infant
- **Pediatrics:**
  - Safety, adherence, and resistance were evaluated in a single-arm, open-label clinical trial (ATN 113) of 67 HIV-1 uninfected at-risk adolescent men who have sex with men received emtricitabine/tenofovir disoproxil fumarate once daily for HIV-1 PrEP
  - In the ATN 113 trial, HIV-1 seroconversion occurred in 3 subjects. Tenofovir diphosphate (DP) levels in dried blood spot assays indicate that these subjects had poor adherence
  - Adherence to study drug, as demonstrated by tenofovir DP levels in dried blood spot assays, declined markedly after Week 12 once subjects switched from monthly to quarterly visits, suggesting that adolescents may benefit from more frequent visits and counseling

Reminder About the Use of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP: Confirming and Regularly Reconfirming Negative HIV-1 Status

- Emtricitabine/tenofovir disoproxil fumarate should be used to reduce the risk of acquiring HIV-1 infection only in individuals confirmed to be HIV-1 negative
- A negative HIV-1 status should be confirmed before prescribing emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- Individuals should be regularly tested (at least every 3 months) while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Some individuals, such as adolescents, may benefit from more frequent visits and counseling
- If a screening test indicates possible infection, or symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved or cleared by the FDA as an aid in the diagnosis of HIV-1, including acute or primary HIV-1 infection
- HIV-1 resistance mutations may emerge in individuals with undetected HIV-1 infection who are taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP

Drug Interactions

- Coadministration of emtricitabine/tenofovir disoproxil fumarate with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir

For further details about emtricitabine/tenofovir disoproxil fumarate drug interactions, please see Prescribing Information for emtricitabine/tenofovir disoproxil fumarate in back pocket.

Use the Checklist for Prescribers: Initiation of Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg for HIV-1 Pre-exposure Prophylaxis (PrEP) and the Agreement Form for Initiating Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg for HIV-1 Pre-exposure Prophylaxis (PrEP) to help manage and counsel individuals about the correct and safe use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

For more information about emtricitabine/tenofovir disoproxil fumarate and its indication for HIV-1 PrEP, please see the Prescribing Information, including the BOXED WARNING, and the Medication Guide. For more information about the REMS program for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, please log on to www.ftc-tdf-preprems.com. You may also obtain additional information and educational materials about the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP at 1-800-625-7471.

Post-Training Review Questions

1. Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should be used only:

a. As part of a comprehensive HIV-1 prevention strategy that includes other preventive measures since emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection

b. In individuals who have been counseled to strictly adhere to their emtricitabine/tenofovir disoproxil fumarate daily dosing schedule since the effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 infection is strongly correlated with adherence and measurable drug levels

c. In individuals who have a confirmed negative HIV-1 test prior to initiating and routinely while taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP

d. All of the above

2. Which of the following statements is false?

a. Emtricitabine/tenofovir disoproxil fumarate should be used for HIV-1 PrEP only in individuals confirmed to be HIV-1 negative

b. Emtricitabine/tenofovir disoproxil fumarate is indicated for HIV-1 PrEP to reduce the risk of acquiring HIV-1 infection through injection drug use

c. Women taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP should not breastfeed their babies if acute HIV-1 infection is suspected

d. Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is not always effective in preventing HIV-1 infection

3. Which of the following items are not included on the Checklist for Prescribers: Initiation of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP)?

a. Perform HBV screening test

b. Perform testing for TB

c. Confirm negative HIV-1 status of the individual

d. Confirm creatinine clearance is ≥60 mL/min

4. Hepatic function should be monitored closely in:

a. HBV-infected individuals who discontinue emtricitabine/tenofovir disoproxil fumarate

b. All people taking emtricitabine/tenofovir disoproxil fumarate

c. All people who discontinue emtricitabine/tenofovir disoproxil fumarate

d. None of the above

5. In clinical trials evaluating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, which of the following adverse reactions was not common?

a. Abdominal pain

b. Headache

c. Dizziness

d. Decreased weight

6. Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is indicated only for:

a. Men who are at risk for sexually acquired HIV-1 infection

b. Adults and adolescents weighing at least 35 kg who are at risk of acquiring HIV-1 infection by any means

c. Adults and adolescents weighing at least 35 kg who are at risk of acquiring HIV-1 infection through injection drug use

d. Adults and adolescents weighing at least 35 kg who are at risk for sexually acquired HIV-1 infection

7. The Agreement Form for Initiating Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-exposure Prophylaxis (PrEP) provides which of the following information:

a. A list of activities that put individuals at risk for sexually acquired HIV-1 infection

b. A confirmation that the prescriber has discussed the risks and benefits of using emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP with the uninfected individual

c. A signature from the individual asserting that the prescriber has explained the risks and benefits of taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, including the need for adherence and a comprehensive prevention strategy, which includes safer sex practices

d. All of the above

Answer key: 1–d; 2–b; 3–b; 4–a; 5–c; 6–d; 7–d

Help uninfected individuals learn more about emtricitabine/tenofovir disoproxil fumarate for HIV-1 pre-exposure prophylaxis (PrEP)

To mail, fold so that the address shows on the outside and then seal.
Or fax to 781-451-4888.

- ☐ I have completed the training for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- ☐ I am willing to participate in the Knowledge, Attitude, and Behavior REMS survey
- ☐ I have prescribed emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP
- ☐ I have not prescribed emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP

If you would like additional educational materials about emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, please select which ones you want and how many you would like us to send to you.

	Quantity:		
☐ Important Safety Information for Adults Who Don't Have HIV	☐ 10	☐ 25	☐ 50
☐ Important Safety Information for Adolescents Who Don't Have HIV	☐ 10	☐ 25	☐ 50
☐ Important Safety Information for Healthcare Providers	☐ 10	☐ 25	☐ 50
☐ Safety Information Fact Sheet	☐ 10	☐ 25	☐ 50
☐ Checklist for Prescribers	☐ 10	☐ 25	☐ 50
☐ Agreement Form	☐ 10	☐ 25	☐ 50
☐ Training Guide for Healthcare Providers	☐ 10	☐ 25	☐ 50

Your full name and degree: _____

Street address: _____

City: _____ State: _____ ZIP: _____

Your practice or clinic name: _____

Your specialty: _____

Telephone: _____ E-mail: _____

Terms and Conditions

The Emtricitabine/Tenofovir Disoproxil Fumarate Sponsor(s) and its authorized agents agree only to use the above information for purposes of fulfilling your request(s) and will not transfer your information to any other party unless required to do so for the sole purpose of completing your request(s).

REMS-SSS-0028 05/18

MOISTEN GLUE STRIP AND FOLD TO SEAL.

((POCKET))

Notes

Reference: TRUVADA [package insert]. Foster City, CA: Gilead Sciences, Inc; 2018.

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