Disoproxil Fumarate Tablets

**1.INDICATIONS AND USAGE**

Disoproxil fumarate tablet (containing 200 mg of FTC and 300 mg of TDF) once daily taken orally with or without food.

**2. DOSAGE AND ADMINISTRATION**

Use Emtricitabine and Tenofovir disoproxil fumarate tablets to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-1 negative. (2.4)

Postmarketing Experience

**3. CLINICAL STUDIES**

Clinical trials evaluating TDF in pediatric and adolescent subjects were conducted. Under normal circumstances, BMD increases during childhood and adolescence and continues to increase into young adulthood. (3)

**4. ADVERSE REACTIONS**

Gastrointestinal Disorders

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Grade</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>≥3+</td>
<td>Mild</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>≥3+</td>
<td>Mild</td>
</tr>
</tbody>
</table>

**5. USE IN SPECIFIC POPULATIONS**

HIV-positive infants born to HIV-positive women who have discontinued Emtricitabine and Tenofovir disoproxil fumarate tablets. Individuals infected with HBV who have discontinued Emtricitabine and Tenofovir disoproxil fumarate tablets. (8.4)

**6. MULTIPLE HIV-1 TESTING**

Most HIV-1 tests only detect anti-HIV antibodies and may not identify HIV-1 during the acute stage of infection. Prior to initiating Emtricitabine and Tenofovir disoproxil fumarate tablets, perform multiple HIV-1 tests in individuals about and support their efforts in reducing sexual risk behavior. (8.4)

**7. DRUG INTERACTIONS**

Concomitant use of Emtricitabine and Tenofovir disoproxil fumarate tablets and other drugs may result in known or potentially unknown drug interactions. (7.2)

**8. NONCLINICAL TOXICOLOGY**

Animal reproduction studies have not been conducted with Emtricitabine and Tenofovir disoproxil fumarate tablets. (8.1)

**9. CLINICAL PHARMACOLOGY**

After receipt by the body of an oral dose of tenofovir, the drug is absorbed from the gastrointestinal tract and enters the circulation. (12.3)

**10. POSTMARKETING EXPERIENCE**

Although postmarketing data suggest no increase in risk of major birth defects, available data from the APR show no significant difference in the overall risk of major birth defects between women exposed to FTC alone or FTC in combination with TDF compared to women exposed to FTC alone or FTC in combination with TDF. (8.1)

**11. PATIENT PACKAGE INSERT**

A broader and continuing discussion of the potential benefits and risks of prescribing Emtricitabine and Tenofovir disoproxil fumarate tablets to reduce the risk of acquiring HIV-1 is provided in the PATIENT PACKAGE INSERT. (5.2)

**12. MECHANISM OF ACTION**

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). (12.1)

**13. CLINICAL PHARMACOLOGY**

Pharmacokinetics

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Dose</th>
<th>Effect</th>
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<tbody>
<tr>
<td>FTC</td>
<td>PO</td>
<td>200  mg</td>
<td>Mild</td>
</tr>
<tr>
<td>TDF</td>
<td>PO</td>
<td>300  mg</td>
<td>Mild</td>
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**14. PHARMACODYNAMICS**

Postmarketing Experience

**15. CLINICAL STUDIES**

Clinical trials evaluating TDF in pediatric and adolescent subjects were conducted. (14.1)

**16. ADVERSE REACTIONS**

Gastrointestinal Disorders

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**17. USE IN SPECIFIC POPULATIONS**

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**18. MULTIPLE HIV-1 TESTING**

Most HIV-1 tests only detect anti-HIV antibodies and may not identify HIV-1 during the acute stage of infection. Prior to initiating Emtricitabine and Tenofovir disoproxil fumarate tablets, perform multiple HIV-1 tests in individuals about and support their efforts in reducing sexual risk behavior. (8.4)

**19. DRUG INTERACTIONS**

Concomitant use of Emtricitabine and Tenofovir disoproxil fumarate tablets and other drugs may result in known or potentially unknown drug interactions. (7.2)

**20. NONCLINICAL TOXICOLOGY**

Animal reproduction studies have not been conducted with Emtricitabine and Tenofovir disoproxil fumarate tablets. (8.1)

**21. CLINICAL PHARMACOLOGY**

After receipt by the body of an oral dose of tenofovir, the drug is absorbed from the gastrointestinal tract and enters the circulation. (12.3)

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**24. MECHANISM OF ACTION**

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). (12.1)
Emtricitabine and Tenofovir Disoproxil Fumarate Tablets include:

- Do not use Emtricitabine and Tenofovir Disoproxil Fumarate if seal over bottle opening is broken or missing.

- Store Emtricitabine and Tenofovir Disoproxil Fumarate Tablets at room temperature between 68°F to 77°F.

- Severe liver problems.

- Too much lactic acid is a serious but rare medical problem.

- Inform individuals using Emtricitabine and Tenofovir disoproxil fumarate tablets for HIV-1 treatment or HIV-1 PrEP that there is an increased risk of bone problems (osteoporosis) and fractures (including those of the wrist, leg, or spine) in individuals with HIV-1 infection.

- Increase in liver enzymes was observed in some clinical trials. The risk of severe liver problems is increased in individuals with abnormal liver function tests or with a family history of liver disease.

- Although studies have not been conducted specifically in pregnant women taking Emtricitabine and Tenofovir disoproxil fumarate tablets, these medications are not recommended for preterm labor and delivery in pregnant women.

- Inform individuals of the importance of taking Emtricitabine and Tenofovir disoproxil fumarate tablets on a regular dosing schedule and strict adherence to HIV-1 treatment.

- Never suppressed is defined as a CD4+ cell count of less than or equal to 200 cells/mm³ at week 48.

- Beneficial effects in adolescent subjects failing treatment with tenofovir in combination with either FTC or lamivudine, and either abacavir or didanosine. Therefore, it is recommended that these medications be taken as part of a combination regimen to prevent or delay the development of resistance.