### Tenofovir Disoproxil Fumarate / Lamivudine / Efavirenz Tablets

#### 300 mg / 300 mg / 600 mg

**Warning**

- Do not use if you are allergic to efavirenz, lamivudine, or any of the excipients in Tenofovir Disoproxil Fumarate/Lamivudine/Efavirenz Tablets.
- Tenofovir Disoproxil Fumarate/Lamivudine/Efavirenz Tablets should not be used with other antiretroviral agents that contain efavirenz, unless it is considered necessary.

#### Contraindications

- Use is contraindicated in patients with severe renal impairment (creatinine clearance < 30 ml/min).
- Patients with a known history of mitochondrial disorders (e.g., mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes).

#### Precautions

- Patients with HIV-1 infection and underlying hepatic disease should be monitored closely for signs and symptoms of hepatic decompensation.
- Fosamprenavir/ritonavir, lopinavir/ritonavir, indinavir/ritonavir, and amphotericin B, foscarnet, ganciclovir, pentamidine, and vancomycin are not recommended for use with Tenofovir Disoproxil Fumarate/Lamivudine/Efavirenz Tablets.

#### Interactions

<table>
<thead>
<tr>
<th>Medication</th>
<th>Effect</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosamprenavir/ritonavir</td>
<td>↓</td>
<td>Co-administration should be avoided.</td>
</tr>
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<td>Lopinavir/ritonavir</td>
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<td>↓</td>
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</tr>
</tbody>
</table>

#### Administration

- Tenofovir Disoproxil Fumarate/Lamivudine/Efavirenz Tablets should be taken once daily, with or without food.
- The dose reduction for Tenofovir Disoproxil Fumarate is considered necessary, especially in patients with impaired renal function, when used in combination with other nephrotoxic medications or when the patient’s creatinine clearance is < 40 ml/min.

#### Therapeutic areas Interaction

<table>
<thead>
<tr>
<th>Medication</th>
<th>Interaction</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir (400 mg q.d.) / efavirenz</td>
<td>↑</td>
<td>Consider switching to atazanavir/ritonavir as an alternative.</td>
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<td>Itraconazole</td>
<td>↓</td>
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</tr>
<tr>
<td>Posaconazole (400 mg b.i.d.) / tenofovir</td>
<td>↓</td>
<td>Consider switching to atazanavir/ritonavir as an alternative.</td>
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<tr>
<td>Raltegravir single dose</td>
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</tbody>
</table>

#### Adverse reactions

- The most common adverse reactions include nausea, diarrhea, and headache.
- Other rare adverse reactions include bone abnormalities, lactic acidosis, and mitochondrial damage.

#### Summary

- Tenofovir Disoproxil Fumarate/Lamivudine/Efavirenz Tablets are indicated as anti-retroviral therapy for the treatment of HIV-1 infection in adults.
- The optimal management of HIV infection should be determined by the healthcare provider, taking into account the patient’s individual characteristics and the presence of other co-morbid conditions.

#### References

- For the use as a Registered Medical Practitioner or a Hospital or a Laboratory only.
Efavirenz

**Rifabutin (300 mg q.d) / Artemisinin and its halofantrine / efavirenz Lumefantrine, Quinine / efavirenz No formal interaction study (600/250 mg q.d.) / Pyrimethamine / Proguanil, / efavirenz (0.035 mg + 0.25 mg)

HORMONAL CONTRACEPTIVES

LIPID LOWERING AGENTS

Available Artemisinin and its halofantrine. No formal interaction studies

↓ Buprenorphine AUC expected when co-treating with efavirenz. Patients of DMPA was not altered due to co-treatment with efavirenz. 64% (active)

↓ Rosuvastatin is largely excreted in urine and less than 1% of the dose was excreted in urine as unchanged efavirenz. Supported by studies, there is no evidence for need to monitor lamivudine in addition to hormonal contraceptives. Because of the long half-life of efavirenz, use of adequate contraceptive measures is recommended. Hormonal contraceptives may be periodically monitored. Lamivudine/Efavirenz can be monitored.

Carbamazepine AUCss: 47% expected to be lowered in co-treatment with efavirenz. Lamivudine/Efavirenz should be co-administered without dose adjustment and can be monitored.

Efavirenz and lamivudine were found to be inhibitors of lamivudine resistance. Lamivudine is used as the negative control in this study. No clinically significant effects were observed in lamivudine resistance and lamivudine resistance following co-treatment with efavirenz.

**Antiviral Activities**

Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that inhibits HIV-1 reverse transcriptase in a manner similar to nevirapine and delavirdine. It acts as a competitive inhibitor of the enzyme, and at concentrations that are tenfold higher than the mean clinical plasma levels, efavirenz displayed a 100-fold greater potency than nevirapine and a 10-fold greater potency than delavirdine. However, the clinical significance of pretreatment with these drugs is not yet known. Therefore, pretreatment with efavirenz is not recommended.

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