HIV 200 mg when it is coadministered with

Nervous System Symptoms

1. INDICATIONS AND USAGE

4. ADVERSE REACTIONS

3. DOSAGE FORMS AND STRENGTHS

5. WARNINGS AND PRECAUTIONS

Tablets

5.8 General Disorders and Administration Site Conditions

Bone Mineral Density

5.6 Nervous System Symptoms

2.2 ·

5% 6% 9% 22%

Bone Mineral Density

5.8 General Disorders and Administration Site Conditions

Aggressive reactions, agitation, delusions, emotional lability, mania, neurosis, paranoia, psychosis, suicide, catatonia

Allergic reactions

2.3 ·

3.1 ·

5.2 ·

5.4 Hepatotoxicity: Monitor liver function tests before and during

Patients who experience central nervous system symptoms such as dizziness, impaired concentration, and/or drowsiness should avoid potentially

5.7 ·

interactions with other antiretrovirals and for 12 weeks after

similar trends were observed in chronic hepatitis-B infected adolescent subjects aged 12 years to less than 18 years. In all pediatric trials, skeletal

5.7 Nervous System Symptoms

5.7 Nervous System Symptoms

Bone Mineral Density

5.8 General Disorders and Administration Site Conditions

Efavirenz may cause fetal harm when administered during the first trimester of pregnancy. Advise adults and adolescents of childbearing potential

interactions with other antiretrovirals and for 12 weeks after

5.8 General Disorders and Administration Site Conditions

Bone Mineral Density

5.8 General Disorders and Administration Site Conditions

Aggressive reactions, agitation, delusions, emotional lability, mania, neurosis, paranoia, psychosis, suicide, catatonia

Allergic reactions
Table 5

<table>
<thead>
<tr>
<th>Drug</th>
<th>Plasma Concentration</th>
<th>Impact of Renal Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFV</td>
<td>In urine, so impact minimal.</td>
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</table>

Pharmacokinetics of EFV, FTC, and tenofovir have not been fully evaluated in the elderly (65 years of age and older). Plasma proteins were reached in 6 to 10 days. In 35 HIV-1 infected subjects receiving EFV 600 mg once daily, steady-state C was 12.9 ± 3.7 mcM (mean ± SD), C in vitro, and the binding is independent of concentration over the range of 0.01 to 25 mcg/mL. Approximately 70 to 80% of the

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Carbamazepine, Boceprevir, Simvastatin, and Nevirapine and PIs (amprenavir, indinavir, nelfinavir, ritonavir, and saquinavir), additive to synergistic effects were observed. Tenofovir i. Compared with didanosine (enteric-coated) 400 mg administered alone under fasting conditions.

Evidence of renal toxicity was noted in 4 animal species administered tenofovir and TDF. Increases in serum creatinine, BUN, glycosuria, and C of coadministered drugs are shown in Table 7.

**Precautions (5.4) and Drug Interactions (7)**

Advise patients that efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets may interact with many drugs; therefore, advise patients to not to discontinue efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets without first informing their healthcare provider. All patients

**PATIENT COUNSELING INFORMATION**

Keep efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and all other medicines out of reach of children. This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Inactive Ingredients:

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and some medicines may interact with each other causing serious side effects.

There are several precautions to keep in mind:

- **Severe liver problems.**
- **Rash.**
- **If you have heart problems**
  - fast or abnormal heartbeat
  - being short of breath or fast breathing

If you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your

**For more information about side effects see the section,**

**Warnings and Precautions (5.12)**

Changes in body fat distribution or accumulation have happened in some people taking HIV-1 medicines, including an

**Storing and Disposing of Medicines**

Keep out of reach of children. Do not throw away any medication unless you are told to do so. Disposal of medicines under certain circumstances may be required by state and local law. If you are not sure what to do, contact your pharmacist. The patient information leaflet is to be given to the patient or to the person prescribed the medicine. For more information, contact the manufacturer.

**If you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your**

**If you have dizziness, trouble concentrating or sleepiness, do not drive a car, use machinery, or do anything that needs you to be alert.**

**If you have changes in vision, especially with reading, writing, or driving, your healthcare provider may advise you to stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.**

**Remember**

This medicine may help you live longer. However, efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets will not cure your HIV-1 infection. It is important that you take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets regularly to get the most benefit. It is important that you take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets regularly to get the most benefit.

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