Efavirenz tablets, USP

DRUG INFORMATION

Class: Non-nucleoside Reverse Transcriptase Inhibitor

Mechanism of Action
Efavirenz is an orphan drug approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV-1 infection. It is available in a single tablet form with a potency of 600 mg of efavirenz per tablet.

Efavirenz is an inhibitor of the enzyme reverse transcriptase, which is responsible for converting HIV-1 RNA to DNA. By inhibiting this enzyme, efavirenz helps to prevent the replication of HIV-1 and the progression of HIV-1-related disease.

Drug Interactions

Efavirenz has a number of potential drug interactions, including:

- **CYP2B6 Inhibitors**: Efavirenz may increase the levels of other medications that are metabolized by CYP2B6, such as cyclosporine and tacrolimus.
- **CYP2C19 Inhibitors**: Efavirenz may increase the levels of other medications that are metabolized by CYP2C19, such as fluconazole and lamotrigine.
- **CYP3A4 Inhibitors and Inducers**: Efavirenz may interact with other medications that are metabolized by CYP3A4, such as ritonavir-boosted atazanavir.

Efavirenz has also been shown to increase the levels of other medications that are metabolized by CYP1A2, such as propranolol.

Dosage and Administration

The recommended dosage of efavirenz is 600 mg once daily, taken with food or warm milk. The dosage should be adjusted based on the patient's weight and the presence of hepatic or renal impairment.

Efavirenz can be taken with or without food, but it is recommended to take it with food or warm milk to minimize the risk of gastrointestinal side effects.

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Efavirenz is administered as a single tablet, 600 mg once daily, with food or warm milk. The dosage should be adjusted based on the patient's weight and the presence of hepatic or renal impairment.

Efavirenz is contraindicated in patients with a history of hypersensitivity to efavirenz or any of its components.

Efavirenz does not affect the ability to drive or to use machinery.

Efavirenz is not recommended for use in women who are pregnant or breastfeeding. It may cause harm to the fetus if taken during pregnancy. It is also not recommended for use in women who are breastfeeding.

Efavirenz has been shown to cause serious psychiatric adverse reactions, including depression, suicide ideation, and delirium.

Efavirenz has been shown to cause serious liver injury, including hepatic failure.

Efavirenz has been shown to cause serious skin reactions, including rashes and hypersensitivity reactions.

Efavirenz has been shown to cause serious marrow depression, including neutropenia and anemia.

Efavirenz has been shown to cause serious immune reconstitution, including immune reconstitution inflammatory syndrome (IRIS).
<table>
<thead>
<tr>
<th>Dose</th>
<th>Effect</th>
<th>Nervous system symptoms</th>
<th>Nausea</th>
<th>Coadministered Drug</th>
<th>Plasma C mean % change</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mg qd x 14 days</td>
<td>↓ 8%</td>
<td>↔ dizziness, difficulty concentrating</td>
<td>13%</td>
<td>↓</td>
<td>(mean % change)</td>
</tr>
<tr>
<td>150 mg q 12 h x 150 mg qd x 14</td>
<td>↑</td>
<td>↔</td>
<td>100 mg bid</td>
<td>↔</td>
<td>(mean % change)</td>
</tr>
<tr>
<td>300 mg</td>
<td>↑</td>
<td>↔</td>
<td>200 mg q 12 h x 5%</td>
<td>↑</td>
<td>(mean % change)</td>
</tr>
<tr>
<td>500 mg q 12 h x 233.98</td>
<td>↑</td>
<td>↔</td>
<td>200 mg q 12 h x 60</td>
<td>↑</td>
<td>(mean % change)</td>
</tr>
<tr>
<td>600 mg qd x 14</td>
<td>↑</td>
<td>↔</td>
<td>10 mg qd x 7%</td>
<td>↓</td>
<td>(mean % change)</td>
</tr>
<tr>
<td>NA = not available.</td>
<td>↓</td>
<td>↔</td>
<td></td>
<td>↓</td>
<td>(mean % change)</td>
</tr>
</tbody>
</table>

### Table 8: Effect of Coadministered Drug on Efavirenz Plasma C

- **Indications increase**: Increase in plasma concentration of efavirenz.
- **Indications decrease**: Decrease in plasma concentration of efavirenz.
- **Indicates decrease**: Decrease in plasma concentration of efavirenz.
- **Indicates increase**: Increase in plasma concentration of efavirenz.

**Drug Interaction Studies**

- **Efavirenz**:
  - **Indications increase**: Increase in plasma concentration of efavirenz.
  - **Indications decrease**: Decrease in plasma concentration of efavirenz.

- **Indications increase**:
  - **Atorvastatin**: Increase in plasma concentration of efavirenz.
  - **Artemether**: Increase in plasma concentration of efavirenz.
  - **Indinavir**: Increase in plasma concentration of efavirenz.
  - **Bupropion**: Increase in plasma concentration of efavirenz.
  - **Saquinavir**: Increase in plasma concentration of efavirenz.

- **Indications decrease**:
  - **Diltiazem**: Decrease in plasma concentration of efavirenz.
  - **Desacetyl metabolite**: Decrease in plasma concentration of efavirenz.
  - **Total active drug**: Decrease in plasma concentration of efavirenz.

- **Efavirenz**:
  - **Indications increase**: Increase in plasma concentration of efavirenz.
  - **Indications decrease**: Decrease in plasma concentration of efavirenz.

### Long-term resistance surveillance (average 52 weeks, range 4 to 106 weeks) analyzed 28 matching baseline and virologic failure isolates.

### Discontinued for adverse events

### Nervous system symptoms

- **Tiredness**: Tiredness is a common side effect of efavirenz.

### Barrier forms of birth control may include latex or polyurethane condom, contraceptive sponge, diaphragm with spermicide,

### Study PACTG 382 was an open-label study to evaluate the pharmacokinetics, safety, tolerability, and antiviral activity of efavirenz in

### Long-term carcinogenicity studies in mice and rats were carried out with efavirenz. Mice were dosed with 0, 25, 75, 150, or 300 mg/kg/

### Efavirenz tablets:

- **Keep efavirenz tablets and all medicines out of the reach of children.**
- **Do not take efavirenz tablets if you are currently taking elbasvir and grazoprevir (ZEPATIER**
- **Hallucinations [seeing or hearing things that others do not see or hear]** may occur months to years after beginning efavirenz tablets therapy. These symptoms may become worse if you drink
- **Your doctor can tell you if it is safe to take efavirenz tablets with**

### Table 7 (effect

### Distribution

- **Room Temperature**.

### Notes:

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### References:

- **Indicates increase**
- **Indicates decrease**
- **95% CI.**

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