Each film-coated tablet contains: Efavirenz, USP 600 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Made in India
Efavirenz Tablets (600 mg)

**Indications and Usage**
Efavirenz is indicated for:
- Initial treatment of HIV-1 infection in adults and pediatric patients aged 3 years and older.
- Treatment of HIV-1 infection in adults and pediatric patients aged 3 years and older with at least 1 baseline regimen failed or with lifethreatening conditions.

**Warnings and Precautions**

- **Hypersensitivity:** Efavirenz is contraindicated in patients who have had a previous allergic reaction to efavirenz.
- **Central Nervous System Symptoms:** Fifty-three percent (53%) of patients receiving efavirenz in controlled trials reported central nervous system symptoms.

**Drug Interactions**

- **Pharmacokinetic Interactions:** Efavirenz may increase the plasma levels of other drugs, such as lamivudine, indinavir, and ritonavir.
- **Pharmacodynamic Interactions:** Efavirenz can interact with other antiretrovirals, such as zidovudine (ZDV) and lamivudine (LAM).

**Dosing and Administration**

- **Adults and Children:** Efavirenz is available in tablets of 600 mg. The recommended dose is 600 mg once daily.

**Adverse Reactions**

- **Hepatic:** Liver enzyme monitoring should be considered for patients without pre-existing hepatic dysfunction or other identifiable risk factors.
- **Dermatological:** Rash, including Stevens-Johnson syndrome and toxic epidermal necrolysis, may occur.

**Additional Information**

- **Breastfeeding:** Efavirenz is not recommended for breastfeeding.
- **Pregnancy:** There is no information available regarding the use of efavirenz in pregnant women.

**Legal Information**

- **Patent Information:** Efavirenz is a registered trademark of Gilead Sciences, Inc.

**References**

- **Clinical Trials:** Studies evaluating the efficacy and safety of efavirenz in clinical trials.

**Other Important Information**

- **Patient Instructions:** Patients should be instructed on the proper use and storage of efavirenz tablets.
- **Drug Poisoning:** Treatment of overdose with efavirenz should consist of general supportive measures, including monitoring of vital signs and hemodynamic stability.

**Tables and Figures**

- **Table of Efavirenz Tablets (600 mg):** Dosage and Administration.
- **Figure 1:** Chemical Structure and Formula of Efavirenz.

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**Adverse Reactions**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Efavirenz (n=1,008)</th>
<th>Control (n=1,008)</th>
<th>Efavirenz (n=1,008)</th>
<th>Control (n=1,008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash</td>
<td>63.6%</td>
<td>8.7%</td>
<td>63.6%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12.8%</td>
<td>12.4%</td>
<td>12.8%</td>
<td>12.4%</td>
</tr>
<tr>
<td>Nausea</td>
<td>10.5%</td>
<td>6.3%</td>
<td>10.5%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Nervous system</td>
<td>9%</td>
<td>6.8%</td>
<td>9%</td>
<td>6.8%</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>7.7%</td>
<td>6.1%</td>
<td>7.7%</td>
<td>6.1%</td>
</tr>
</tbody>
</table>

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**Drug Interactions**

- **Cimetidine:** Cimetidine doses may need to be increased.
- **Indinavir:** Indinavir doses may need to be decreased.
- **Lamivudine:** Lamivudine doses may need to be increased.

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**Pharmacokinetics**

- **Absorption:** Efavirenz is absorbed following oral administration.
- **Distribution:** Efavirenz is distributed throughout the body, including the central nervous system.

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**Clinical Trials**

- **Study ACTG 364:** NRTI-experienced, NNRTI- and LAM-.