Each tablet contains: Nevirapine, USP (anhydrous) 100 mg

Usual Dosage: See accompanying prescribing information.

Tablets must be swallowed whole and must not be chewed, crushed, or divided. 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

Rx only
30 Tablets

NDC 0378-6950-93

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Prompt “LOT” & “EXP” will be printed together with Variable Data Coading.
Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Code No.: MH/DRUGS/AD/089

Each tablet contains:
Nevirapine, USP (anhydrous) 100 mg

Usual Dosage: See accompanying prescribing information.

Tablets must be swallowed whole and must not be chewed, crushed, or divided.
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

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Prompt “LOT” & “EXP” will be printed together with Variable Data Coading.

NDC 0378-6950-77

Nevirapine Extended-release Tablets

100 mg

Rx only 90 Tablets
Each tablet contains: Nevirapine, USP (anhydrous) 100 mg

Usual Dosage: See accompanying prescribing information.

Tablets must be swallowed whole and must not be chewed, crushed, or divided.

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.]

This container is not intended for dispensing for household use.

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

Made in India

VARNISH FREE AREA
Prompt “LOT” & “EXP” will be printed together with Variable Data Coding.

Rx only
500 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
Keep container tightly closed.

Code No.: MH/DRUGS/AD/089

PHARMACIST: Dispense the Medication Guide provided separately to each patient.
### Anticonvulsants:

- Carbamazepine
- Clonazepam
- Phenobarbital
- Phenytoin
- Valproic acid
- Lamotrigine
- Topiramate
- Mepobarbital
- Oxcarbazepine
- Levetiracetam
- Lacosamide
- Zonisamide
- Vigabatrin
- Gabapentin

- Telaprevir (Incivek®)
- Atazanavir (Reyataz®)
- Lopinavir and ritonavir (Kaletra®) once daily

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#### Table 1: Recommended Nevirapine Extended-release Tablets Dosing for Pediatric Patients

<table>
<thead>
<tr>
<th>BSA (m²)</th>
<th>Nevirapine Extended-release Tablets Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.001 to 0.01</td>
<td>200 mg once daily (1 x 200 mg)</td>
</tr>
<tr>
<td>0.0117 to 0.04</td>
<td>400 mg once daily (1 x 400 mg)</td>
</tr>
<tr>
<td>Greater than or equal to 0.04</td>
<td>600 mg once daily (1 x 600 mg)</td>
</tr>
</tbody>
</table>

**Pediatric Patients: Dosing**

- Pediatric patients may be dosed using nevirapine extended-release 400 mg or 100 mg tablets.

**Dosage and Administration:**

- Adult patients must initiate therapy with one 200 mg tablet of immediate-release nevirapine once daily for the first 14 days, then the approved dose for their body size.

**Warnings and Precautions:**

- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including nevirapine.
- People who have abnormal liver test results before starting nevirapine treatment and people with liver problems, especially:
  - Women with CD4 count below 200 cells/mm³
  - Older patients
  - Those treated with other antiretroviral therapies

**Adverse Reactions:**

- Most common adverse reactions:
  - Rash
  - Fatigue
  - Musculoskeletal symptoms

- Serious adverse reactions:
  - Liver toxicity
  - Nervous system toxicity
  - Renal toxicity

**Drug Interactions:**

- Nevirapine may interact with other HIV medications, including protease inhibitors, and other medications.

**Dosage Adjustments:**

- Adjustments may be necessary based on renal function and other medical conditions.

**Overdosage:**

- Symptoms: Nausea, vomiting, diarrhea, dizziness, confusion, agitation, seizures, respiratory depression, myoclonus, convulsions.

- Management:
  - Supportive care
  - Hemodialysis

**Special Populations:**

- Pregnancy: Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Children: Use with caution and monitor closely.

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**References:**

Atazanavir trial. The median EC₅₀ value was 63 nM (range 14-302 nM, n = 29) against clinical isolates of HIV-1 clades A, B, C, D, F, G, and H, and nevirapine at 400 mg per day.

Race

The concomitant drug on plasma nevirapine steady-state concentrations was estimated by comparison to historical controls.

Resistance:

Mononuclear cells, monocyte-derived macrophages, and lymphoblastoid cell lines. In an assay using human embryonic kidney 293 cell line, nevirapine demonstrates inhibitory activity on reverse transcriptase (R) and blocks the RNA-dependent and DNA-dependent DNA polymerase activities by causing a disruption in the conformation of the enzyme. The IC₅₀ of nevirapine against reverse transcriptase is less than 25 micromolar. Therefore, nevirapine may have minimal inhibitory effect on other substrates of CYP3A.

HIV-1 that were primarily (93%) clade B clinical isolates from the United States. The 99th percentile EC₅₀ value was 470 nM in this group.

Nevirapine pharmacokinetics in HIV-1-infected adults do not appear to change with age (range 18 to 68 years); however, the concomitant drug on plasma nevirapine steady-state concentrations was estimated by comparison to historical controls.

Atazanavir (Reyataz®)

• atazanavir (Reyataz®)

Fosamprenavir 1400 mg BID

• fosamprenavir (Lexapro®)

Lopinavir/ Ritonavir

• lopinavir/ritonavir (Kaletra®)

Ritonavir 600 mg BID

• ritonavir (Norvir®)

Zidovudine 100 mg to 200 mg BID 200 mg QD x 14 days;

Ketoconazole 400 mg QD 200 mg QD x 14 days;

Ritonavir 600 mg BID 200 mg QD x 14 days;

Atazanavir 300 mg BID

Fosamprenavir 1400 mg BID 200 mg BID.

Subjects were treated with immediate-release nevirapine prior to trial entry. 400 mg QD x 14 days

Nevirapine comes in three different forms. Your doctor will prescribe the form that is written for health professionals. Nevirapine comes in three different forms. Your doctor will prescribe the form that is written for health professionals.

Nevirapine extended-release tablets. If you would like more information, talk with your doctor or pharmacist. Nevirapine extended-release tablets. If you would like more information, talk with your doctor or pharmacist.

HIV medicine.

What is the most important information I should know about nevirapine?

The most common side effects of nevirapine include:

• rash

• changes in blood tests

• changes in body fat

• changes in the解散 of allergies

Most rashes happen in the first 6 weeks of taking nevirapine. If you have a rash that bothers you or lasts more than 7 days, call your doctor.

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HIV medicine.
What is nevirapine?
Nevirapine is a prescription medicine used with other HIV medicines to treat HIV (Human Immunodeficiency Virus) in adults and in children who are 6 years of age to less than 18 years of age.

Nevirapine tablets and nevirapine extended-release tablets are a type of HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Nevirapine extended-release tablets are not for use in children less than 16 years of age.

Nevirapine tablets may be taken with or without food. You may take nevirapine tablets with a glass of milk or water.

Nevirapine extended-release tablets should be swallowed whole. Do not crush, break, or divide nevirapine extended-release tablets.

What should I tell my doctor before taking nevirapine?
Tell your doctor about all the medicines you take, including prescription and nonprescription medicines.

Nevirapine does not cure HIV or AIDS and you may continue to have symptoms of your HIV infection. Nevirapine reduces the risk of developing life-threatening HIV-related illnesses and some AIDS-defining conditions. Nevirapine may not reduce the transmission of HIV to other people.

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Nevirapine does not cure HIV infection or AIDS.
Nevirapine does not cure HIV or AIDS and you may continue to experience illnesses associated with HIV infection, including opportunistic infections. You should remain under the care of a doctor when using nevirapine.

Nevirapine is only for people diagnosed with HIV. If you have not been diagnosed as HIV positive, then do not take nevirapine.

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Nevirapine has been prescribed for you because your doctor has decided that its benefits are greater than its risks. If you do not understand why you are taking nevirapine, talk to your doctor.

Nevirapine can harm your unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while taking nevirapine.

Nevirapine is not for use in children less than 16 years of age. If you are a woman with CD4+ counts higher than 400 cells/mm³, you and your doctor will decide whether starting nevirapine is right for you.

Nevirapine can cause serious side effects including:

- Changes in body fat that can happen in some people who take antiretroviral therapy. These changes may increase your risk of or a man with CD4+ counts higher than 400 cells/mm³, you and your doctor will decide whether starting nevirapine is right for you.

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