Nevirapine Tablets are effective. See full prescribing information for NEVIRAPINE.

## HIGHLIGHTS OF PRESCRIBING INFORMATION

- **INDICATIONS AND USAGE**

  Nevirapine is indicated for the treatment of human immunodeficiency virus (HIV-1) infection in adults who are not otherwise receiving antiretroviral therapy, and in pediatric patients 6 years of age and older. Nevirapine is indicated for the treatment of pediatric patients with symptomatic infection who are not otherwise receiving antiretroviral therapy.

### DOSAGE FORMS AND STRENGTHS

- **1** Tablet

### OVERDOSAGE

- The potential for drug interactions must be considered prior to treatment.

### WARNINGS AND PRECAUTIONS

- **Hepatotoxicity and Hepatic Impairment**
  - Nevirapine use can result in hepatotoxicity, including fatal cases, and can cause severe or life-threatening skin reactions.
  - Nevirapine should be used with caution in patients with liver disease.

### ADVERSE REACTIONS

- **Skin Reactions**
  - Nevirapine use can cause severe or life-threatening skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis.
  - Nevirapine use can cause rash, which can be severe or life-threatening.

### DRUG INTERACTIONS

- **Drug Interactions**
  - Nevirapine is metabolized by the CYP3A4 enzyme system and can interact with other drugs that are also metabolized by this enzyme system.
  - Nevirapine can increase the risk of adverse events when used with other drugs that are metabolized by the CYP3A4 enzyme system.

### PATIENT COUNSELING INFORMATION

- **Infants and Children**
  - Nevirapine use can cause severe or life-threatening skin reactions, including Stevens-Johnson syndrome.

### PRECAUTIONS

- **Hepatitis and Hepatic Impairment**
  - Nevirapine use can cause hepatitis, hepatic necrosis, and hepatic failure.

### DOSAGE AND ADMINISTRATION

- **Adult Patients**
  - Nevirapine is administered orally as two 200 mg tablets twice daily for 14 days as a lead-in period. After the lead-in period, Nevirapine is administered orally as one 200 mg tablet twice daily in combination with other antiretroviral agents.

### USE IN SPECIFIC POPULATIONS

- **Pediatric Patients**
  - Nevirapine use can cause severe or life-threatening skin reactions, including Stevens-Johnson syndrome.

### FULL PRESCRIBING INFORMATION

- For complete prescribing information, see full Prescribing Information.

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### USE IN SPECIFIC POPULATIONS

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from animal fertility studies conducted in rats, Nevirapine may reduce fertility in females of repro-
centration were low, ranging from 734 to 1140 ng/mL. The estimated nevirapine dose of 704 to 682

Reactions (6.2) and Clinical Studies (14.2) [see Data]

Nevirapine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) with activity against Human

Nevirapine is readily absorbed (greater than 90%) after oral administration in healthy volunteers

Expert dosing of nevirapine at 150 mg/m

Depomedroxyprogesterone, Depo-Provera, Norpro, and other contraceptive preparations, may

Pharmacokinetic and pharmacodynamic studies also suggest dual inhibition of 3A4 and B6.

Concurrent use of nevirapine and a CYP3A inhibitor is not recommended.

Nevirapine is a white to off-white crystalline powder with the mo-

The mechanism of action of nevirapine is mediated by interacting with the viral reverse transcriptase, inactivating the enzyme, thereby blocking nucleic acid synthesis.

Any patient experiencing a rash should have their liver enzymes (AST, ALT) evaluated immediately. If liver tests are abnormal or if symptoms of hepatic involvement develop, stop nevirapine and restart at a lower dose as tolerated.

Nevirapine is contraindicated in patients who have experienced a rash or hypersensitivity reaction with a previous dose of nevirapine; in patients with severe hepatic impairment; and in patients with known sensitivity to Nevirapine or any of its excipients.

The Centers for Disease Control and Prevention recommend that HIV-1 infected mothers in the

In these studies with human liver microsomes have shown that nevirap-

and clinical significance of this accumulation is not known. No

Concurrent use of nevirapine and ritonavir is not recommended. Both drugs are substrates of CYP3A4, which may result in an increased risk of toxicity.

Nevirapine is metabolized by CYP3A4, CYP2B6, CYP1A2, and other cytochrome P450 isozymes. Its primary metabolites are glucuronide and sulfate conjugates, which are excreted in the urine. The plasma concentration of unchanged nevirapine is approximately 10% of the total plasma drug concentration.

Animal studies have shown that nevirapine is widely distributed to nearly all tissues and readily absorbed by the placenta. After oral administration, nevirapine is absorbed in a dose-dependent manner. The extent of absorption ranges from 50% to 100% with a median of 75%.

Cisapride Plasma concentrations may be

Motility agents:

Toward a better understanding of the biologic effects of nevirapine, a 100-fold decrease in susceptibility to nevirapine in cell culture compared to baseline, and had one or more of the following mutations: K103N, V106A, V108I, Y181C, Y188C, and G190A.

the mean difference in nevirapine Cmin during pregnancy as compared to postpartum. In these studies, the mean difference in nevirapine Cmin during pregnancy as compared to

identified by enhanced toxicity [2].

The mean area under the plasma concentration-time curve (AUC) of nevirapine was increased in healthy volunteers with cirrhosis or decompensated cirrhosis (Child-Pugh B). In cirrhosis, the mean AUC of nevirapine increased by 117% and 191% for Child-Pugh A and B, respectively. In decompensated cirrhosis, the mean AUC increased by 251%.

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The Cmax and AUC of nevirapine were higher in Black subjects compared to non-Black subjects. In Trial 1100.1486, the mean Cmax of nevirapine in Black subjects was 131% higher than in non-Black subjects, and the mean AUC was 78% higher.

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