INDICATIONS AND USAGE

Nevirapine is an NNRTI indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 13 years of age and older who are treatment-naive or who are inadequately treated with other antiretroviral agents. Nevirapine may be used after recovery from nevirapine-induced rash and hepatitis to treat HIV-1 infection in adult and pediatric patients who are not taking multiple doses of nevirapine concurrently. Nevirapine oral suspension is indicated for the treatment of HIV-1 infection in children 6 to 17 years of age with body weight of 15 kg to 40 kg who are treatment-naive or who are inadequately treated with other antiretroviral agents.

CLINICAL PHARMACOLOGY

See 17 for PATIENT COUNSELING INFORMATION.

MECHANISM OF ACTION

Nevirapine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that binds to the HIV-1 reverse transcriptase and prevents the synthesis of viral DNA. Nevirapine is not a substrate for the cytochrome CYP3A4 isoenzyme system and therefore is not metabolized by cytochrome CYP3A4.

ADVERSE REACTIONS

The most common adverse reactions reported in clinical trials with nevirapine are rash and elevation of liver enzymes. See 4.4 for dermatologic reactions; 5.2 for hepatic transaminase elevations; and 6.1, 6.2, and 12.2 for the management of rash and hepatic transaminase elevations.

Pediatric Use

In clinical trials, the most frequent adverse reactions in pediatric patients were rash (38% of patients), diarrhea (27%), nausea (21%), headache (13%), and vomiting (11%).

CONTRAINDICATIONS

Nevirapine is contraindicated in patients with a history of a severe drug reaction to nevirapine, a history of rash associated with transaminase elevations, or a history of rash associated with transaminase elevations in the setting of post-exposure prophylaxis (PEP) with nevirapine.

PREGNANCY

Nevirapine is contraindicated in women who are pregnant or who are planning to become pregnant within 6 months after discontinuing nevirapine use.

Nursing Mothers

Nevirapine is contraindicated in breastfeeding women due to the risk of drug-induced hepatotoxicity in the neonate.

FEMALE REPRODUCTIVE POTENTIAL

Nevirapine is contraindicated in women of childbearing potential who are not taking hormonal contraceptives and do not have a demonstrated negative pregnancy test.

MENOPAUSAL FEMALES

Nevirapine is contraindicated in menopausal females who are not taking hormonal contraceptives and do not have a demonstrated negative pregnancy test.

DISCONTINUATION

If a patient discontinues nevirapine for any reason, the patient's current antiretroviral therapy should be monitored carefully for evidence of drug-induced toxicity. If a patient discontinues nevirapine, the patient's current antiretroviral therapy should be monitored carefully for evidence of drug-induced toxicity. To avoid re-initiation of nevirapine, the patient's current antiretroviral therapy should be monitored carefully for evidence of drug-induced toxicity.

ADDITIONAL INSTRUCTIONS

The pharmacokinetics of nevirapine have not been evaluated in patients with CrCL less than 20 mL per min. An increase in body weight may result in a dose reduction of up to 50% in adults. The dose of nevirapine should be increased by 50% in patients with body weight less than 50 kg. The appropriate doses of the combination of nevirapine and other antiretroviral agents should be determined by the dosing regimen of the antiretroviral agent being used in combination with nevirapine. The dose of nevirapine should be increased by 50% in patients with body weight less than 50 kg. The appropriate doses of the combination of nevirapine and other antiretroviral agents should be determined by the dosing regimen of the antiretroviral agent being used in combination with nevirapine.

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