Nevirapine Tablets, USP

8. USE IN SPECIFIC POPULATIONS

2.2. Pediatric Patients

*Total daily dose should not exceed 15 mg/kg/day.

Trials 1037, 1038, 1046 have shown that Nevirapine significantly increases the CD4 cell counts in children with HIV-1 infection. The increase is particularly seen in children whose CD4 cell counts are lower than the study entry criteria of 200 cells/mm². Nevirapine should be started at a dose of 15 mg/kg/day and increased to 30 mg/kg/day at 28 days in children whose CD4 cell counts fell between 200 and 350 cells/mm². If CD4 cell counts are between 350 and 500 cells/mm², the dose may be added in every 28 days until a total daily dose of 30 mg/kg/day is reached.

11.7.1.2. Safety through pregnancy

Nevirapine is contraindicated during pregnancy. Nevirapine is not recommended for use during pregnancy.

4.3. Lactation

Nevirapine is not recommended for use in breastfeeding women.

5.1. Hepatitis

Nevirapine may cause liver damage, including severe liver damage.

11.8. Pregnancy

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