Nevirapine tablets for oral suspension 50mg and 100mg

What is Nevirapine?
Nevirapine is an NNRTI indicated for combination antiretroviral treatment of HIV-1 infection. The most common adverse reaction is rash. In adults the incidence of rash is 14.8% vs. 5.9% with placebo, with Grade 2 rashes observed in 4.3% vs. 2.0% of patients. Nevirapine is contraindicated for use during pregnancy. Nevirapine monotherapy is not recommended because the recommended dose has already been calculated and displayed based on weight band (see Table 1). The total daily dose should never exceed 150 mg. The recommended oral dosage of scored Nevirapine in HIV-1-infected pediatric patients is shown in Table 1. Take Nevirapine with food to minimize gastrointestinal upset.

Dosage Adjustment
The recommended oral dosage of scored Nevirapine in HIV-1-infected pediatric patients is shown in Table 1. Take Nevirapine with food to minimize gastrointestinal upset.

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WARNING: LIFE THREATENING (INCLUDING FATAL) HEPATOTOXICITY and SKIN REACTIONS

• Severe skin or hypersensitivity reactions (5.2)

The most serious adverse reactions associated with nevirapine are hepatitis/hepatic failure, Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis. Nevirapine contains phenylalanine, which should be avoided in patients with phenylketonuria.

5.6 Fat Redistribution
Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral edema, and increased subcutaneous fat may occur in a subset of patients taking HIV-1 protease inhibitors (PIs) in association with weight gain. Nevirapine should be continued even if patients cannot tolerate the adverse effects of redistribution/accumulation of body fat due to PI therapy. Nevirapine may be used with other antiretroviral agents that increase body fat redistribution/accumulation, such as lopinavir/ritonavir. Nevirapine monotherapy is not recommended because the recommended dose has already been calculated and displayed based on weight band (see Table 1). An increase in body weight may be a useful indicator of response in patients who have not had the beneficial effects of PI therapy on body weight.

5.5 Immune Reconstitution Syndrome
During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections (such as pulmonary tuberculosis or mycobacterium avium complex [MAC]) and to previously undiagnosed opportunistic infections (e.g., cryptosporidiosis or pneumocystis pneumonia). The patients at greatest risk of hepatic events, including potentially fatal events, are women with high CD4+ cell counts. In general, patients with high CD4+ counts are at increased risk of immune reconstitution syndrome. In addition, patients with high CD4+ cell counts may be at increased risk of hepatic events. Immune reconstitution syndrome is associated with the rapid restoration of CD4+ cell counts and may occur in combination with fever, chills, malaise, anorexia, nausea, jaundice, liver tenderness or hepatomegaly, with or without initially abnormal serum transaminase levels. The majority of immune reconstitution reactions occur within the first 12 weeks of starting combination antiretroviral treatment. Immune reconstitution syndrome may be treated with the specific treatment of a particular infection and with the initiation or increased dosing of corticosteroids. The speciﬁc treatment of immune reconstitution syndrome and the associated conditions is provided in the prescribing information for the specific antiretroviral medication.

2.1 Pediatric Patients
The recommended oral dosage of scored Nevirapine in HIV-1-infected pediatric patients is shown in Table 1. Take Nevirapine with food to minimize gastrointestinal upset.

2.3 Dosage Adjustment
The recommended oral dosage of scored Nevirapine in HIV-1-infected pediatric patients is shown in Table 1. Take Nevirapine with food to minimize gastrointestinal upset.

2.4 Known Adverse Reactions
The most serious adverse reactions associated with nevirapine are hepatitis/hepatic failure, Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis. Nevirapine contains phenylalanine, which should be avoided in patients with phenylketonuria.

13. NONCLINICAL TOXICOLOGY
See full prescribing information for complete boxed warning.