Nevirapine (NVP)

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Formulations

Oral Suspension: 10 mg/mL

Tablet: Immediate-release 200 mg

Generic Formulations

- 10-mg/mL suspension
- Immediate-release 200-mg tablet

Dosing Recommendations

Note: Nevirapine (NVP) is often used as part of newborn antiretroviral prophylaxis or presumptive HIV therapy regimens to prevent perinatal transmission of HIV. Doses of NVP used for prophylaxis can differ substantially from doses used for treatment. See Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV.

Child and Adolescent Dose

- When initiated in children aged >2 years, NVP is given once daily for 2 weeks to allow autoinduction of the enzymes involved in its metabolism. This may not be necessary in children aged ≤2 years.[a]
- Dosing is available for neonates as young as 32 weeks' gestation. For more information, see Special Considerations for Dosing: Neonates and Premature Infants below.

Immediate-Release Tablets and Oral Suspension

Gestational Age of 32 to <34 Weeks

- Birth to age 2 weeks: NVP 2 mg/kg per dose twice daily (no lead-in dosing)[a]
- Age 2–4 weeks: NVP 4 mg/kg per dose twice daily
- Age 4–6 weeks: NVP 6 mg/kg per dose twice daily
- Age >6 weeks: NVP 200 mg/m^2 of body surface area (BSA) per dose twice daily; only make this dose increase for infants with confirmed HIV infection.
- This dosing strategy is recommended by the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panel) based on the review of pharmacokinetic (PK) modeling and simulation data. This dosing strategy has not been evaluated in clinical trials and is not approved by the U.S. Food and Drug Administration (FDA).

Selected Adverse Events

- Rash, including Stevens-Johnson syndrome
- Symptomatic hepatitis, including fatal hepatic necrosis[b]
- Severe systemic hypersensitivity syndrome with potential for multisystem organ involvement and shock

Special Instructions

- The total daily dose should not exceed NVP 400 mg daily.
- The extended-release tablet formulation of NVP is no longer available.
- The oral suspension must be shaken well before administering, and it should be stored at room temperature.
- NVP can be given with or without food.
- NVP-associated skin rash usually occurs within the first 6 weeks of therapy. If rash occurs during the initial 14-day lead-in period, do not increase the dose until the rash resolves (see Major Toxicities below).

Gestational Age of 34 to <37 Weeks

- Birth to age 1 week: NVP 4 mg/kg per dose twice daily (no lead-in dosing)[a]
- Age 1 week to 4 weeks: NVP 6 mg/kg per dose twice daily
- Age >4 weeks: NVP 200 mg/m^2 of BSA per dose twice daily; only make this dose increase for infants with confirmed HIV infection.
- This dosing strategy is recommended by the Panel based on the review of PK and safety data on this regimen from clinical trials. This dosing strategy is not approved by the FDA.

Gestational Age of ≥37 Weeks to Age of <1 Month

- Birth to age 4 weeks: NVP 6 mg/kg per dose twice daily (no lead-in dosing)[a]
- Age >4 weeks: NVP 200 mg/m^2 of BSA per dose twice daily; only make this dose increase for infants with confirmed HIV infection.
- This dosing strategy is recommended by the Panel based on the review of PK and safety data on this regimen from clinical trials. This dosing strategy is not approved by the FDA.

Aged ≥1 Month to <8 Years

- NVP 200 mg/m^2 of BSA per dose twice daily after lead-in dosing.[a] In children aged ≤2 years, some experts initiate NVP without lead-in dosing (maximum dose of immediate-release tablets is NVP 200 mg twice daily).

Aged ≥8 Years

- NVP 120 mg to 150 mg/m^2 of BSA per dose twice daily after lead-in dosing[a] (maximum dose of immediate-release tablets is NVP 200 mg twice daily).
- When adjusting the dose for a growing child, the absolute dose need not be decreased as the child reaches age 8 years; rather, the absolute dose can be left static to achieve the appropriate mg-per-m^2 dose as the child grows, assuming no adverse effects emerge.

NVP Used in Combination With Lopinavir/Ritonavir (LPV/r)

- A higher dose of LPV/r may be needed in children who also are receiving NVP (see the Lopinavir/Ritonavir section).

- If NVP dosing is interrupted for >14 days, NVP should be restarted with once-daily dosing for 14 days, followed by escalation to the full twice-daily regimen (see Dosing Considerations: Lead-In Dosing below).
- Most cases of NVP-associated hepatic toxicity occur during the first 12 weeks of therapy; frequent clinical and laboratory monitoring, including liver function tests, is important during this period (see Major Toxicities below).

Metabolism/Elimination

- NVP is a substrate and inducer of cytochrome P450 (CYP) 3A4 and CYP2B6. More than 80% of an NVP dose is eliminated in urine as uridine diphosphate glucuronosyltransferase–derived glucuronidated metabolites.

NVP Dosing in Children With Hepatic Impairment

- NVP should not be administered to children with moderate or severe hepatic impairment.

NVP Dosing in Children With Renal Failure Who Are Receiving Hemodialysis

- An additional dose of NVP should be given following each dialysis session.

[a] NVP is usually initiated at a lower dose that is increased in a stepwise fashion. NVP induces CYP metabolizing enzymes, which results in increased drug clearance. The stepwise increase in dose reduces the frequency of rash. Clinicians generally should initiate therapy with the immediate-release tablet formulation once daily instead of twice daily for the first 14 days of therapy. If no rashes or other adverse effects emerge after 14 days of therapy, increase the dose of NVP to the age-appropriate full dose of the immediate-release tablet formulation administered twice daily. For example, the recommended oral dose for infants and children aged ≥1 month to <8 years is NVP 200 mg/m^2 of BSA once daily for the first 14 days, followed by NVP 200 mg/m^2 of BSA twice daily thereafter. However, in children aged ≤2 years, some experts initiate NVP without lead-in dosing (see the Dosing Considerations: Lead-In Dosing and Special Considerations for Dosing: Neonates and Premature Infants sections below).

[b] Severe life-threatening and, in rare cases, fatal hepatotoxicity—including fulminant and cholestatic hepatitis, hepatic necrosis, and hepatic failure—has occurred in people who were taking NVP. These toxicities are less common in children than adults. Most cases occur during the first 12 weeks of therapy and may be associated

with rash or other signs or symptoms of hypersensitivity reaction (HSR). NVP **should be discontinued and not restarted** in children or adults who develop symptomatic hepatitis, severe transaminase elevations, or HSRs.

Special Considerations for Dosing: Neonates and Premature Infants

Nevirapine (NVP) is now used primarily for the treatment or presumptive treatment of HIV in infants, including those born preterm (see What to Start: Antiretroviral Treatment Regimens Recommended for Initial Therapy in Infants and Children With HIV and Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV).

The pharmacokinetic (PK) and safety of NVP during the first weeks of life were evaluated as part of IMPAACT P1115. This study demonstrated that NVP dosed at 6 mg/kg twice daily for infants ≥37 weeks gestational age (GA) and 4 mg/kg twice daily for 1 week and 6 mg/kg twice daily thereafter for infants 34 to <37 weeks GA achieved concentrations appropriate for treatment.[1] Among 438 infants (389 infants ≥37 weeks GA), measured NVP concentrations were above the minimum HIV treatment target (3 mcg/mL) in 90% of infants at Week 1 and 87% of infants at Week 2. Grade 3 and 4 adverse events possibly related to treatment occurred in 7% of infants (with neutropenia and anemia being the most common) but did not lead to NVP cessation.

PK modeling and simulation were performed with partial data from IMPAACT P1106 and P1115 to determine appropriate NVP dosing in premature infants 32 to <34 weeks GA. GA and postnatal age were significantly correlated with NVP oral clearance; thus, the authors recommended a GA-based starting dose for premature infants treated with NVP and a stepwise increase in dosing at 2-week intervals.[2] These data might underestimate potential drug toxicity in infants of 32 to <34 weeks GA because the doses used to develop the model were lower than the doses now recommended. NVP is shown to be safe in infants >34 weeks GA, so the risk of toxicity in infants 32 to <34 weeks GA seems low. The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panel) considers that this risk–benefit ratio may justify the use of this dose in premature infants 32 to <34 weeks GA.

The Early Infant Treatment Study in Botswana started 40 infants with HIV ≥35 weeks GA on NVP 6 mg/kg twice daily (without lead-in dosing) along with zidovudine and lamivudine at a median age 2 days (range 1–5 days). NVP was switched to lopinavir/ritonavir at Week 2, 3, 4, or 5 according to delivery GA. Although NVP trough concentrations were below the therapeutic target (3,000 ng/mL) for 50% of 2-week measurements, 37 of 40 infants (92.5%) had an HIV RNA decline.[3] Among this cohort, 38 of 40 participants survived to 96 weeks with a preserved CD4 T lymphocyte (CD4) cell count and low reservoir, which was predicted by a low pre–antiretroviral therapy (ART) reservoir size.[4] Providers who consider initiating treatment in premature infants or in infants aged <2 weeks should weigh the risks and benefits of using unapproved ART dosing and should incorporate case-specific factors, such as exposure to antiretroviral prophylaxis.

Drug Interactions

Additional information about drug interactions is available in the Liverpool HIV Drug Interaction Checker.

- *Metabolism:* NVP is metabolized by and induces hepatic cytochrome P450 (CYP) 3A and CYP2B6; autoinduction of metabolism occurs in 2 to 4 weeks of NVP dosing, leading to a 1.5-fold to 2-fold increase in NVP clearance. Multiple drug interactions with NVP are possible. Some genetic polymorphisms of CYP2B6 are associated with increased NVP plasma concentrations. The prevalence of CYP2B6 polymorphisms varies among populations and may

contribute to differences in NVP exposure. See the Efavirenz section for more information on how polymorphisms can alter metabolic enzyme activity.

- NVP should not be coadministered to children who are receiving atazanavir (ATV) (with or without ritonavir) because NVP substantially decreases ATV exposure.
- NVP increases the metabolism of lopinavir (LPV). A dose adjustment of LPV is recommended when the two drugs are coadministered (see the Lopinavir/Ritonavir section).
- Before NVP is initiated, a child's medication profile should be carefully reviewed for potential drug interactions.

Major Toxicities

The following toxicities are seen with chronic dosing.

- More common: Skin rash (some severe cases have required hospitalization, and some cases have been life-threatening, including instances of Stevens-Johnson syndrome and toxic epidermal necrolysis), fever, nausea, headache, and elevated hepatic transaminases. In the two largest case series of NVP-induced Stevens-Johnson syndrome in children, the incidence rate was estimated between 1.4% and 7.1%.[5,6] NVP should be discontinued and not restarted in children or adults who develop severe rash, rash with constitutional symptoms (i.e., fever, oral lesions, conjunctivitis, or blistering), or rash with elevated levels of hepatic transaminases. NVP-associated skin rash usually occurs within the first 6 weeks of therapy. If rash occurs during the initial 14-day lead-in period, do not increase the dose until rash resolves. However, the risk of developing NVP resistance with extended lead-in dosing is unknown, and this concern must be weighed against the current antiviral response and a person's overall ability to tolerate the regimen.
- *Less common (more severe):* Symptomatic hepatitis, including fatal hepatic necrosis, and severe systemic hypersensitivity syndrome with potential for multisystem organ involvement and shock. These toxicities are less common in children than adults. Most cases occur during the first 12 weeks of therapy and may be associated with rash or other signs or symptoms of hypersensitivity reaction (HSR). Risk factors for NVP-related hepatic toxicity in adults include baseline elevation in serum transaminase levels, hepatitis B or hepatitis C virus infection, female sex, and higher CD4 count at time of therapy initiation (CD4 count >250 cells/mm^3 in adult females and >400 cells/mm^3 in adult males). Children with CD4 percentages >15% have a threefold increase in the risk of rash and hepatotoxicity after initiating NVP.[7] HSRs have been reported, including, but not limited to, severe rash or rash accompanied by fever, blisters, oral lesions, conjunctivitis, facial edema, muscle or joint aches, general malaise, and significant hepatic abnormalities. NVP **should be discontinued and not restarted** in children or adults who develop symptomatic hepatitis, severe transaminase elevations, or HSRs.
- *Less common (more severe):* In a cross-sectional study of 201 children with HIV aged 6 to 16 years, 43% of whom had hypertension, the use of NVP was associated with left ventricular hypertrophy (LVH) (adjusted odds ratio 3.14; confidence interval 1.13–8.72; $P = 0.03$) but not left ventricular diastolic dysfunction.[8] The median duration on ART in this cohort was 4.7 years (interquartile range [IQR] 2.6–6.4 years). Most participants (76.6%) were receiving a regimen that included two nucleoside reverse transcriptase inhibitors and a non-nucleoside reverse transcriptase inhibitor (NNRTI). However, the use of NVP was not associated with LVH in a more recent study by the same authors. LVH has been associated with NVP use in adults.[9,10]

Resistance

The International AIDS Society–USA maintains a list of updated resistance mutations, and the Stanford University HIV Drug Resistance Database offers a discussion of each mutation.

Pediatric Use

Approval

NVP is approved by the U.S. Food and Drug Administration (FDA) for treatment of HIV in children from infancy (aged ≥15 days) onward. The Panel recommends dosing for preterm infants based on either PK and safety data from clinical trials, or PK modeling and simulation; however, dosing strategies for preterm infants are not FDA approved.

The NVP extended-release tablet formulation (400 mg) was previously approved by the FDA for use in children aged ≥6 years but is now discontinued.

Efficacy in Clinical Trials

Randomized clinical trials evaluating the efficacy of NVP in children with HIV are of historical significance. Refer to archived versions of the Pediatric Antiretroviral Guidelines for details.

General Dosing Considerations

Body surface area (BSA) has traditionally been used to guide NVP dosing in infants and young children. It is important to avoid underdosing NVP, because a single point mutation (K103N) in the HIV genome may confer NNRTI resistance to both NVP and efavirenz. Younger children (aged ≤8 years) have higher apparent oral clearance than older children. To achieve drug exposures that are comparable to those seen in children aged >8 years, younger children require higher doses of NVP than older children.[11,12] Because of this, it is recommended that children aged <8 years receive NVP 200 mg/m^2 of BSA per dose twice daily (the maximum dose of the immediate-release tablet formulation is NVP 200 mg twice daily). For children aged ≥8 years, the recommended dose of the immediate-release tablet formulation is NVP 120 mg/m^2 of BSA per dose (with a maximum dose of NVP 200 mg) administered twice daily.

When adjusting the dose for a growing child, the milligram dose need not be decreased (from NVP 200 mg to NVP 120 mg/m^2 of BSA) as the child reaches 8 years of age; rather, the milligram dose can be left static if no adverse effects emerge and the dose achieves the appropriate mg/m^2 of BSA dose as the child grows. Some practitioners dose NVP at 150 mg/m^2 of BSA every 12 hours, regardless of age, as recommended in the FDA-approved product label. Regardless of age, the maximum dose should never exceed NVP 200 mg twice daily for immediate-release formulations of NVP.

Dosing Considerations: Lead-in Dosing

Underdosing during the lead-in period may have potentially contributed to the poorer performance of NVP in the IMPAACT P1060 trial. This potential for underdosing, which can increase the risk of resistance, led to a re-evaluation of lead-in dosing in children who have never received NVP. Traditionally, NVP is initiated with an age-appropriate dose that is given only once daily instead of twice daily (NVP 200 mg/m^2 of BSA in infants aged ≥15 days and children aged <8 years, using the immediate-release formulations) during the first 2 weeks of treatment to allow the autoinduction of the liver enzymes CYP3A and CYP2B6, which are involved in NVP metabolism.

Studies have previously indicated potential for greater drug toxicity without lead-in dosing; however, most of these studies have been performed in adult cohorts.[13] The CHAPAS-1 trial[14] randomized 211 children with a median (IQR) age of 5 (2–9) years to initiate ART with immediate-release NVP without a lead-in dose (participants received an age-appropriate dose twice daily) or with a lead-in

dose (participants received an age-appropriate dose once daily) for 2 weeks, followed by the standard twice-daily dosing of the immediate-release formulation of NVP. Children were followed for a median of 92 weeks (with a range of 68–116 weeks), and no difference emerged in the frequency of Grade 3 or 4 adverse events between the two groups. The group that initiated NVP without a lead-in dose had a statistically significant increase in the incidence of Grade 2 rash, but most participants were able to continue NVP therapy after a brief interruption. Through 96 weeks, a similar percentage of participants in both groups reached the CD4 count and virologic failure endpoints.

After children in CHAPAS-1 had been on NVP for 2 weeks, investigators conducted a substudy that examined NVP plasma concentrations 3 to 4 hours after a morning dose of NVP. Among children aged <2 years, 3 of 23 children (13%) who initiated at full dose had subtherapeutic NVP levels (<3 mg/L) at 2 weeks compared with 7 of 22 children (32%) who initiated at half dose ($P = 0.16$). No rash events occurred in the substudy group of participants aged <2 years; in the parent CHAPAS study, a strong age effect on rash occurrence was seen, with the risk of rash increasing with age. These findings suggest that a lead-in dose may not be necessary in young children.[15]

The standard practice has been to reinitiate half-dose NVP for another 2 weeks in children who have interrupted therapy for 7 days or longer; however, given the current understanding of NVP resistance, the half-life of CYP enzymes,[16] and the results of CHAPAS-1, the Panel recommends restarting full-dose NVP in children who interrupt therapy for 14 days or less.

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