Zidovudine (ZDV, Retrovir)

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Formulations

Syrup: 10 mg/mL

Capsule: 100 mg

Concentrate for Injection or Intravenous Infusion: 10 mg/mL (Retrovir)

Generic Formulations

- 100-mg capsule
- 10-mg/mL syrup
- 300-mg tablet

Fixed-Dose Combination (FDC) Tablets

- [Generic] Lamivudine 150 mg/zidovudine 300 mg (scored)
- [Generic] Abacavir 300 mg/lamivudine 150 mg/zidovudine 300 mg

When using FDC tablets, refer to other sections of Appendix A. Pediatric Antiretroviral Drug Information for information about the individual components of the FDC. See also Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents.

For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations

Note: Zidovudine (ZDV) is frequently used in neonates to prevent perinatal transmission of HIV. See Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV and Table 13 for information about using ZDV to prevent perinatal HIV transmission.

Recommended Neonatal Dose for Treatment of HIV by Gestational Age at Birth[a]

Gestational Age at Birth	Oral ZDV Dose
≥35 Weeks	**Birth to Age 4 Weeks** • ZDV 4 mg/kg twice daily; *or* • Alternative simplified weight-band dosing

Selected Adverse Events

- Bone marrow suppression leading to anemia and neutropenia, macrocytosis with or without anemia
- Nausea, vomiting, headache, insomnia, asthenia
- Lactic acidosis/severe hepatomegaly with hepatic steatosis
- Lipodystrophy and lipoatrophy
- Myopathy (associated with prolonged use of ZDV) and myositis

Special Instructions

- Give ZDV without regard to food.
- Initial ZDV dose should be based on weight at birth and estimated gestational age at delivery.
- Dose reduction **is not recommended** for anticipated weight loss in the first few weeks of life unless clinically indicated for renal or hepatic impairment.

Simplified Weight-Band Dosing for Infants With a Gestational Age ≥35 Weeks at Birth

Note: The doses in this table provide approximately ZDV 4 mg/kg twice daily from birth to age 4 weeks.

Weight Band	Twice-Daily Volume of ZDV 10 mg/mL Syrup
2 kg to <3 kg	1 mL
3 kg to <4 kg	1.5 mL
4 kg to <5 kg	2 mL

Aged >4 Weeks

- ZDV 12 mg/kg twice daily

≥30 Weeks to <35 Weeks

Birth to Age 2 Weeks

- ZDV 2 mg/kg twice daily

Aged 2 Weeks to 6 Weeks

- ZDV 3 mg/kg twice daily

Aged >6 Weeks

- ZDV 12 mg/kg twice daily

<30 Weeks

Birth to Age 4 Weeks

- ZDV 2 mg/kg twice daily

Aged 4 Weeks to 8 Weeks

- ZDV 3 mg/kg twice daily

Aged >8 Weeks

- ZDV 12 mg/kg twice daily

Note: For infants who are unable to tolerate oral agents, the intravenous dose should be 75% of the oral dose, but the dosing interval should remain the same.

Infant (Aged ≥35 Weeks Postconception and ≥4 Weeks Postdelivery, Weighing ≥4 kg) and Child Dose Weight-Based Dosing for ZDV

Weight	Twice-Daily Dosing
4 kg to <9 kg	12 mg/kg
9 kg to <30 kg	9 mg/kg
≥30 kg	300 mg

- Simplified weight-band dosing is indicated only for infants with gestational age of ≥35 weeks.
- If substantial granulocytopenia or anemia develops in patients who are receiving ZDV, it may be necessary to discontinue therapy until bone marrow recovery is observed. In this setting, some patients may require erythropoietin or filgrastim injections or transfusions of red blood cells.
- Screen patients for hepatitis B virus (HBV) infection before using FDC products that contain lamivudine (3TC). Severe acute exacerbation of HBV infection can occur when 3TC is discontinued; therefore, hepatic function should be monitored for several months after patients with HBV infection stop taking 3TC.

Metabolism/Elimination

- ZDV is eliminated primarily by hepatic metabolism. The major metabolite is ZDV glucuronide, which is renally excreted.
- ZDV is phosphorylated intracellularly to active ZDV triphosphate.

ZDV Dosing in Patients With Hepatic Impairment

- The dose of ZDV may need to be reduced in patients with hepatic impairment.
- Do not use FDC products in patients who have impaired hepatic function.

ZDV Dosing in Patients With Renal Impairment

- A dose adjustment is required for ZDV in patients with renal failure[1] (see the manufacturer's prescribing information and Pharmacokinetics below). Do not use FDC products in patients with creatinine clearance <50 mL/min or in patients who are on hemodialysis.

Alternative Body Surface Area Dosing *Oral* • ZDV 180–240 mg per m^2 of body surface area every 12 hours **Child and Adolescent (Weighing ≥30 kg) and Adult Dose** • ZDV 300 mg twice daily **Lamivudine (3TC)/ZDV** *Child and Adolescent (Weighing ≥30 kg) and Adult Dose* • One tablet twice daily **Abacavir/3TC/ZDV** *Child and Adolescent (Weighing ≥30 kg) and Adult Dose* • One tablet twice daily	

[a] For premature infants who receive an HIV diagnosis, the time to change to the continuation dose varies with postgestational age and clinical status of the infant.

Drug Interactions

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

- *Bone marrow suppressive/cytotoxic agents, including ganciclovir, valganciclovir, interferon alfa, and ribavirin:* These agents may increase the hematologic toxicity of zidovudine (ZDV).
- *Nucleoside analogues that affect DNA replication:* Nucleoside analogues—such as ribavirin—antagonize *in vitro* antiviral activity of ZDV.
- *Doxorubicin:* Simultaneous use of doxorubicin and ZDV **should be avoided.** Doxorubicin may inhibit the phosphorylation of ZDV to its active form.

Major Toxicities

- *More common:* Hematologic toxicity, including neutropenia and anemia, particularly in patients with advanced HIV disease. Headache, malaise, nausea, vomiting, and anorexia. Neutropenia may occur more frequently in infants who are receiving both lamivudine (3TC) and ZDV than in infants who are receiving only ZDV.[2]
- *Less common (more severe):* Myopathy (associated with prolonged use), myositis, and liver toxicity. Cases of lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Fat maldistribution has been observed in patients receiving antiretroviral (ARV) medications.
- *Rare:* Possible increased risk of cardiomyopathy.[3-5]

Resistance

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

Pediatric Use

Approval

Pediatric experience with ZDV—both for treating HIV and for preventing perinatal transmission—is extensive.[6-9] However, the mitochondrial toxicity of ZDV leads many experts to favor the use of abacavir (ABC) or tenofovir alafenamide in cases where the individual's age and the results of viral resistance testing do not restrict the use of these drugs.

Efficacy in Clinical Trials

ZDV—an NRTI (nucleoside reverse transcriptase inhibitor)—has been extensively studied in pediatric clinical trials with other NRTIs (i.e., ABC, 3TC, stavudine) as part of an antiretroviral therapy (ART) regimen. All ZDV-based dual-NRTI regimens had low toxicity and produced good clinical, immunologic, and virologic responses.[10-13]

For second-line ART, ZDV as an NRTI backbone may be less effective than ABC or tenofovir.[14,15] In the NADIA study in adults and adolescents, a higher likelihood of the emergence of dolutegravir (DTG) resistance was seen in the participants receiving ZDV compared to those on tenofovir disoproxil fumarate as an NRTI backbone.[14] Recently, a secondary analysis of the ODYSSEY study in infants, children, and adolescents starting first-line or second-line treatment with DTG-based ART versus standard of care (non-nucleoside reverse transcriptase inhibitor, boosted protease inhibitor, or non-DTG integrase strand transfer inhibitor) was performed. Participants starting second-line DTG-based ART with ZDV were more likely to experience virologic failure than those on an ABC or tenofovir backbone.[15] Because ZDV needs to be taken twice daily, lower adherence may be responsible for the higher virologic failure rates in both children and adults[15] (see Recognizing and Managing Antiretroviral Treatment Failure).

Infants With Perinatal HIV Exposure

The Pediatric AIDS Clinical Trials Group (PACTG) 076 clinical trial[16] demonstrated that administering ZDV to pregnant women and their infants could reduce the risk of perinatal HIV transmission by nearly 70%. See Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV for further discussion on using ZDV to prevent perinatal transmission of HIV. A ZDV dose of approximately 4 mg/kg of body weight every 12 hours is recommended for prevention of perinatal HIV transmission in neonates and infants with gestational ages ≥35 weeks. Infants who have been exposed to HIV but are uninfected should continue on the prophylactic dose for 2 to 6 weeks, depending on their gestational age at time of delivery and the risk assessment for perinatal transmission.

Simplified, alternative weight-band dosing has also been developed, and the rationale for these doses is based on the intracellular metabolism of ZDV (see Pharmacokinetics below). The rate-limiting step in the phosphorylation of ZDV to active ZDV triphosphate is the limited amount of thymidylate kinase. Increasing the dose of ZDV will lead to increased ZDV plasma concentrations and increased intracellular concentrations of ZDV monophosphate, but not to increased concentrations of ZDV diphosphate or ZDV triphosphate.

In 31 infants who received ZDV to prevent perinatal transmission, levels of intracellular ZDV metabolites were measured after delivery. Plasma ZDV and intracellular ZDV monophosphate decreased by roughly 50% between postdelivery Day 1 and Day 28, whereas ZDV diphosphate and ZDV triphosphate remained low throughout the sampling period.[17] ZDV dose is poorly correlated with the active form of ZDV that is found intracellularly. Because of this, a simplified weight-band dosing approach can be used for the first 4 weeks of life in infants with gestational ages ≥35 weeks

(see the dosing table above). This approach should simplify the minor dose adjustments that are commonly made due to changes in infant weight during ZDV use in the first 4 weeks of life and will make it easier for caregivers to administer ZDV oral syrup to their infants. The changes in weight and the small differences in ZDV dose will have minor effects on the intracellular concentrations of ZDV triphosphate.

Infants With HIV Infection

The Early Infant Treatment Study in Botswana evaluated the safety and efficacy of initiation of ART in the first week of life. Forty infants who tested positive for HIV within 96 hours of birth were started on ZDV, 3TC, and nevirapine (NVP) with successful transition to lopinavir/ritonavir (LPV/r) at 2 to 5 weeks after delivery. Early treatment was found to be safe and effective, with most infants achieving and maintaining viral suppression by 24 weeks of age.[18]

For full-term neonates who receive an HIV diagnosis during the first days to weeks of life, the ZDV dose should be increased to the continuation dose at age 4 weeks (see the dosing table above). The activity of the enzymes responsible for glucuronidation is low at birth and increases dramatically during the first 4 to 6 weeks of life in full-term neonates. This increase in metabolizing enzyme activity leads to an increased clearance of plasma ZDV, and the dose of ZDV should be adjusted when ZDV is used to treat HIV after the first 4 weeks in full-term infants.

For premature infants who receive an HIV diagnosis, the time to increase the ZDV dose from the initial dose varies with postnatal age and the clinical status of the neonate. On the basis of population pharmacokinetic (PK) modeling and simulations and data from studies that have evaluated ZDV PKs in premature infants, the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV recommends the following:

- For infants with HIV born at ≥30 weeks to <35 weeks, switch to a dose of ZDV 12 mg/kg twice daily at a postnatal age of >6 weeks.
- For infants born at <30 weeks, switch to ZDV 12 mg/kg twice daily at a postnatal age of >8 weeks.[19]

Clinicians should perform a careful clinical assessment of the infant, evaluate hepatic and renal function, and review concomitant medications before increasing the ZDV dose to the dose recommended for full-term infants.

Pharmacokinetics

ZDV undergoes intracellular metabolism to achieve its active form, ZDV triphosphate. Phosphorylation requires multiple steps: ZDV is phosphorylated by thymidine kinase to ZDV monophosphate, ZDV monophosphate is phosphorylated by thymidylate kinase to ZDV diphosphate, and ZDV diphosphate is phosphorylated by nucleoside diphosphate kinase to ZDV triphosphate. Overall, ZDV PK in infants aged >3 months are like those seen in adults. Although the mean half-life of intracellular ZDV triphosphate (9.1 hours) is considerably longer than that of unmetabolized ZDV in plasma (1.5 hours), once-daily ZDV dosing is not recommended because of the low intracellular ZDV triphosphate concentrations seen with 600-mg, once-daily dosing in adolescents.[20] PK studies, such as PACTG 331, demonstrate that dose adjustments are necessary for premature infants because they have reduced clearance of ZDV compared with the clearance observed in term newborns of similar postnatal ages.[7] ZDV has good central nervous system (CNS) penetration (cerebrospinal fluid–to-plasma concentration ratio is 0.68), and ZDV has been used in children with HIV-related CNS disease.[9]

PK and safety of ZDV, 3TC, and LPV/r in children with HIV and severe acute malnutrition (SAM) were studied in International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) P1092.[21] Steady-state PK, safety, and tolerability were compared in children with HIV with and without SAM. Overall safety and tolerability did not differ between the two cohorts, and similar area-under-the-curve values for ZDV, 3TC, and LPV/r were observed in these children who were dosed according to World Health Organization weight-band dosing recommendations.[21]

ZDV clearance is decreased in patients with impaired renal function. A dose reduction of 50% is recommended for adolescents and adults with renal failure (creatinine clearance [CrCl] <15 mL/min) or on hemodialysis or peritoneal dialysis (see the manufacturer's prescribing information). Although no neonate-specific data exist, based on expert opinion, a similar dose reduction of 50% is recommended in neonates with renal failure (CrCl < 10 mL/min).

The PK of intravenous ZDV in a premature neonate with gestational age of 32 weeks on extra corporal membrane oxygenation (ECMO) has been reported in a single case report. Based on measurements of ZDV plasma concentrations during and after ECMO, the authors concluded that ECMO did not have an impact on ZDV PK and that standard intravenous dosing of ZDV can be used in preterm neonates.[22]

Toxicity

Several studies suggest that the adverse hematologic effects of ZDV may be concentration-dependent, with a higher risk of anemia and neutropenia in patients who have higher mean plasma area-under-the-curve values for ZDV.[6,7,23] A significant reduction in the incidence of hematologic toxicity was observed during a retrospective analysis of infants who received a short course of ZDV (2 weeks) to prevent perinatal HIV transmission.[24] In this study, 137 infants received ZDV for 2 weeks, and 184 infants received ZDV for >2 weeks; of these infants, 168 (91.3%) received 4 weeks of ZDV prophylaxis. The risk of anemia (defined as a Division of AIDS severity grade of mild or higher) was significantly lower in the short-course group at both age 1 month ($P < 0.001$) and age 3 months ($P < 0.001$).[24] For infants who develop significant anemia while receiving ZDV for prevention of perinatal HIV transmission, early discontinuation may be considered for infants who are determined to be at a low risk of transmission after expert consultation. A prospective cohort study conducted in Thailand evaluated the safety of triple ARV neonatal presumptive therapy with ZDV/3TC/NVP for 6 weeks in infants at high risk of acquisition of HIV compared with 4 weeks of monotherapy with ZDV in infants considered at low risk. No significant differences were observed in the incidence of neutropenia, hepatoxicity, or severe anemia between the triple ARV and the ZDV monotherapy groups.[25]

Incidence of hematological toxicity was investigated in the ARROW study, which randomized Ugandan and Zimbabwean children who were ART-naïve to receive either ZDV-containing regimens or ABC-containing regimens. The incidence of severe anemia was similar regardless of ZDV use; this finding suggests that advanced HIV disease contributed to low hemoglobin values. ZDV use was associated with severe neutropenia in a small number of children.[26] In a retrospective study conducted in Ethiopia, an evaluation of predictors of anemia among children on ART[27] was conducted from 2007 to 2017. Study participants receiving ZDV-containing regimens were four times more likely to develop anemia than children receiving ABC-containing regimens. Other predictors of anemia in addition to ZDV in this patient population included tuberculosis, severe immunosuppression, and undernutrition.

ZDV is associated with greater mitochondrial toxicity than ABC and tenofovir disoproxil fumarate.[28,29]

Although the incidence of cardiomyopathy associated with perinatal HIV infection has decreased dramatically since the use of ART became routine, the use of a regimen that contains ZDV may increase the risk.[3,5] Analysis of data from a U.S.-based multicenter prospective cohort

study (PACTG 219/219C) found that ongoing ZDV exposure was independently associated with a higher rate of cardiomyopathy.[3] As part of the Pediatric HIV/AIDS Cohort Study (PHACS)/Adolescent Master Protocol (AMP) study, echocardiogram measurements were collected between 2008 and 2010 in 325 youth aged 7 to 16 years with perinatally acquired HIV infection. An association between ZDV use and increased end-systolic wall stress was observed in this study. The investigators speculate that alterations in cardiac structure in these children could progress to symptomatic cardiomyopathy later in life.[4] A large cohort study to evaluate the prevalence of cardiac dysfunction in children and young adults <26 years of age was conducted in Kenya.[5] Approximately 28% of participants were found to have evidence of early cardiac dysfunction. Left ventricular ejection fraction negatively correlated with prior ZDV exposure, detectable HIV RNA, and elevated interleukin-6 concentrations.[5]

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