Viread Approved for Children 2 and Up

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Viread (tenofovir), Gilead Sciences' nucleotide reverse transcriptase inhibitor, has been approved for children living with HIV, according to a U.S. Food and Drug Administration (FDA) announcement. To facilitate correct pediatric use of the drug, the agency also approved a powder formulation for children between the ages of 2 and 5 and low-dose tablets to meet pediatric dosing needs.

The FDA originally approved Viread in 2001 as a once-daily 300 milligram (mg) tablet for adults living with HIV. In March 2010, the 300 mg dose was approved for use in the United States among adolescents between the ages of 12 and 17.

The new pediatric approval is based on data from a Phase III safety and efficacy clinical trial of a Viread-containing antiretroviral regimen compared to an antiretroviral regimen containing Retrovir (zidovudine) or Zerit (stavudine) in children living with HIV between the ages of 2 and 12. The safety profile observed in the study was consistent with that observed in clinical trials in adults.

In addition to allowing the drug to be prescribed for pediatric HIV, the FDA approved three lower-strength once-daily tablets of Viread in doses of 150 mg, 200 mg and 250 mg for children who can swallow pills. The agency also approved an oral powder formulation of Viread for children between the ages of 2 and 5.

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