

HIV Treatment for Children



Key points:

- Expanding the global supply of HIV treatment available for children is an urgent public health need and a priority for Gilead.
- Gilead is committed to the development of pediatric formulations of its medicines for HIV and as new treatment options advance through our pipeline, we are expediting pediatric research.
- Formulations of Viread® and Emtriva® have been developed and approved for pediatric use by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Globally, an estimated 3.2 million children under age 15 are living with HIV, and an estimated 240,000 become infected each year.¹ Yet only 24 percent of HIV-positive children receive antiretroviral therapy (compared with 38 percent of adults).² A major barrier to expanding treatment for children, particularly infants and toddlers, is the difficulty of developing and manufacturing suitable medicines, including easy-to-swallow and heat-stable antiretroviral formulations that have acceptable palatability for children and are appropriate for use in developing countries.

We also need to be sure that we have a full understanding of the safety profile of our medicines before commencing studies in children. Where possible, we run pediatric trials in parallel with those for adults. However, even though approved by regulators as part of our research and development plans, some studies do not begin until a medicine has undergone regulatory review for an adult indication.

Viread (tenofovir disoproxil fumarate 300 mg) has been approved by the FDA for use in pediatric HIV patients 2 years and older (oral powder formulation for children ages 2-5, lower-strength tablets of 150 mg, 200 mg and 250 mg for children ages 6-12, and full-strength Viread tablets for adolescents ages 12-17). Emtriva (emtricitabine 200 mg) has been approved for infants younger than 3 months (oral solution) and for patients 3 months and older (oral solution or capsules). Gilead's single tablet regimen Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is currently approved for use in adult patients. Its safety and effectiveness have not been established for pediatric patients, but pediatric trials are currently underway. Pediatric studies of the single agents Vitekta® (elvitegravir 150 mg) and Tybost® (cobicistat 150 mg), which are components of Stribild, began in 2014.

Pediatric Medicines for Developing Countries

In addition to our own research, we actively encourage our generic partners to develop dosage forms of our HIV medicines that would be appropriate for children. Since July 2011, we have waived royalty payments on any pediatric formulations produced by our Indian licensing partners for developing countries. The royalty is also waived on generic pediatric versions produced by partners sub-licensed to manufacture Gilead HIV therapies through the Medicines Patent Pool. (More information on generic licensing and the Patent Pool is available [here](#)).

Through these efforts, we hope to help achieve the goal of universal access to treatment for all people, including children, living with HIV.

Gilead is also supporting a number of collaborative research studies, including Public Private Partnerships (PPP) in the developing world that are evaluating our HIV medicines in pregnant women and their infants, including their investigational use for the prevention of mother-to-child transmission of the virus.

References

¹ UNAIDS. Children and HIV. Fact Sheet. July 2014. Available at: http://www.unaids.org/sites/default/files/media_asset/FactSheet_Children_en.pdf.

² UNAIDS. Fast Track: Ending the AIDS Epidemic by 2030. 2014.