Viread Label Revised to Address Treatment of Hep B in Children

The FDA's revision was based on two randomized trials of Viread (tenofovir disoproxil fumarate) use in 2- through 11-year-olds.

December 19, 2018 By Benjamin Ryan

The Food and Drug Administration (FDA) has revised the drug label for Viread (tenofovir disoproxil fumarate) to account for 48-week data from two recent randomized trials of the drug's use for treatment of hepatitis B virus (HBV) in children 2 through 11 years old.

The studies known as Trial 144 and Trial 115 included children with hep B who were at least 2 years old but who had not reached 12 years old.

In Trial 144 in particular, 89 children were treated with doses of Viread that ranged between 8 milligrams per kilogram of bodyweight and a flat dose of 300 mg. After 48 weeks of treatment, 77 percent of the participants had a viral load below 400, compared with 7 percent of a control group. Sixty-six percent of those treated with Viread experienced normalization of their ALT liver enzymes compared with and 15 percent of the controls.

Those treated with Viread made lower gains in their bone mineral density than those in the control group.

Among the 15 children in both trials with a viral load above 400 after 48 weeks of treatment, 14 had no evidence of viral resistance against Viread.

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