FDA Approves Hepatitis C Treatment Mavyret for Children for All Genotypes

May 22, 2019 By Connie M. Welch

April 30, 2019, the U.S. FDA approved hepatitis C treatment Mavyret for children from ages 12 to 17 with all genotypes. Mavyret made by AbbVie was approved for adults in 2017.

Jeffrey Murray, M.D., M.P.H., deputy director of the Division of Antiviral Products in the FDA's Center for Drug Evaluation and Research stated, "Direct-acting antiviral drugs reduce the amount of HCV in the body by preventing the virus from multiplying, and in most cases, they cure HCV infection. Today's approval represents another treatment option for children and adolescents with HCV infection, but for the first time, in all genotypes of HCV."

Mavyret is approved for the treatment of adult or pediatric patients 12 years and older, or who weigh a minimum of 99 pounds. Mavyret is a treatment option for all genotypes and patients without cirrhosis or with compensated (mild) cirrhosis.

Clinical Trial

The safety and efficacy of Mavyret in pediatric patients with hepatitis C were evaluated through clinical research trials of 47 patients with genotypes 1, 2, 3, or 4, without cirrhosis and with mild (compensated) cirrhosis.

Cure Rate Results & Treatment Duration

Clinical results demonstrated 100 percent of patients who were treated for 8 or 16 weeks reported non-detected for the hepatitis C virus and received an SVR12 (sustained virologic response) 12 weeks after completing treatment which is considered cured.

Treatment length depends on previous treatment history, genotype, and cirrhosis status.

For Cirrhosis/Kidney Transplant /Liver Transplant/Genotype 5, 6

The safety and efficacy of Mavyret in pediatrics with cirrhosis, history of kidney and/or liver transplant, or those with genotype 5, or 6 are supported by previous clinical trial research with adults.

Treatment Side Effects

Treatment side effects of Mavyret were reported to be the same as in adults. Common side effects which are; headache, fatigue, nausea, and some with diarrhea. The most common side effects reported were headache and fatigue.

Not Recommended For
Mavyret is not recommended for pediatrics with moderate to severe cirrhosis. Mavyret should not be used on pediatrics taking the drugs atazanavir and rifampin.

Caution
For adult patients with a co-infection of hepatitis C and hepatitis B, hepatitis B has been reported reactive with hepatitis C treatment with direct-acting antivirals and those not receiving hepatitis B antiviral treatment. Hepatitis B reactivation in patients being treated with hepatitis C direct-acting antivirals can result in serious liver problems or death in some patients.

It is recommended all patients be tested for hepatitis B before starting treatment with Mavyret.

Do you have a question or comment about hepatitis C treatment?

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