FDA approves mavyret for children, adolescents with hep C

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(HealthDay)—Mavyret (glecaprevir and pibrentasvir) tablets are now approved to treat all six genotypes of hepatitis C virus (HCV) in children ages 12 to 17 years, the U.S. Food and Drug Administration announced yesterday.

The FDA approved Mavyret to treat HCV in adults in 2017. This new approval marks the first treatment option for all HCV genotypes in children. Dosing information for Mavyret has been updated to include treatment of patients at least 12 years of age and weighing at least 99 pounds who have any of the six identified HCV genotypes with or without cirrhosis. Recommended oral dosage is three tablets containing a total of 300 mg glecaprevir and 120 mg pibrentasvir once daily. Treatment duration depends on an individual patient's treatment history, viral genotype, and cirrhosis status.

Researchers evaluated Mavyret in 47 pediatric patients with HCV genotypes 1 through 4 and with no or mild cirrhosis. Twelve weeks after treatment completion, no virus was detected in any patients who received treatment with Mavyret for eight or 16 weeks. The FDA says previous studies of glecaprevir and pibrentasvir in adults support the safety and efficacy of Mavyret in children with cirrhosis, kidney or liver transplant history, and HCV genotypes 5 and 6.

Headache and fatigue are the most commonly reported adverse reactions with Mavyret. Because hepatitis B virus (HBV) reactivation has been found in HCV/HBV-infected adults treated with HCV direct-acting antivirals, the FDA recommends providers screen patients for HBV before starting Mavyret treatment. The drug is contraindicated in patients taking atazanavir and rifampin and in those with severe cirrhosis.

Approval was granted to AbbVie.

More information: More Information