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Generic Name:

Glecaprevir and pibrentasvir

Trade Name:

Mavyret

Company:

AbbVie

Notes:

FDA approved glecaprevir and pibrentasvir tablets to treat all six genotypes of hepatitis C virus (HCV) in children aged 12 to 17. The combination drug was previously approved to treat HCV in adults in [2017](#).

With this approval, dosing information is provided for treatment of adult or pediatric patients 12 years and older, or weighing at least 99 pounds, who are infected with any of six identified HCV genotypes either without cirrhosis or with compensated cirrhosis.

Safety and efficacy of glecaprevir/pibrentasvir for use with pediatric patients was evaluated during clinical trials of 47 patients with genotype 1, 2, 3 or 4 HCV infection without cirrhosis or with mild cirrhosis. Results demonstrated that 100% of patients who received the drug for 8 or 16 weeks had no virus detected in the blood 12 weeks after finishing treatment, suggesting that patients' infection had been cured.

In pediatric patients with cirrhosis, history of a kidney and/or liver transplant, or genotype 5 or 6 HCV infection, safety and efficacy are supported by previous studies observed in glecaprevir and pibrentasvir in adults. The adverse reactions observed were consistent with those observed in clinical studies in adults.

Treatment duration differs depending on treatment history, viral genotype, and cirrhosis status.

The most common adverse reactions are headache and fatigue. The agent is not recommended for treatment of patients with moderate cirrhosis and contraindicated in patients with severe cirrhosis. It is also contraindicated in patients taking the drugs atazanavir and rifampin.

Hepatitis B virus (HBV) reactivation has been reported in HCV/HBV-coinfected adult patients who were undergoing or had completed treatment with HCV direct-acting antivirals and who were not receiving HBV antiviral therapy. HBV reactivation in patients treated with direct-acting antiviral medicines can result in serious liver problems or death in some patients. Health professionals should screen all patients for evidence of current or prior HBV infection before starting treatment with glecaprevir/pibrentasvir.

Medication Monitor Categories:

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