FDA Approves New Treatment Duration With Mavyret for All Genotypes

October 9, 2019 By Connie M. Welch

The U.S. FDA announced October 1, 2019, Mavyret by AbbVie has been approved to include a new hepatitis C treatment duration of 8 weeks for adults and children over 12 years of age for all genotypes with mild liver damage to compensated cirrhosis.

This hales another victory for improved treatment for hepatitis C.

Jeffrey Murray, MD, deputy director of the division of antiviral products in the FDA's Center for Drug Evaluation and Research stated, "This approval provides a treatment duration of 8 weeks for both pediatric and adult patients with compensated cirrhosis regardless of HCV genotype."

Dr. Murray also added, "Mavyret (Glecaprevir/pibrentasvir) is a combination of direct-acting antiviral drugs that reduce the amount of HCV (hepatitis C virus) in the body to undetected levels by preventing the virus from multiplying, and in most cases, curing HCV infection."

Dose & Requirements

Mavyret is a fixed-dose combination tablet containing glecaprevir 100 mg and pibrentasvir 40 mg. No ribavirin required. The recommended oral dosage of Mavyret is three tablets taken once daily with food.

Genotypes

- For all genotypes: 1, 2, 3, 4, 5, 6 patients without any treatment experience and no cirrhosis, treatment is for 8 weeks.
- Patients without any treatment experience with compensated cirrhosis, treatment is now 8 weeks.
- For all genotypes with decompensated cirrhosis or those with kidney disease, portal hypertension, etc. treatment duration needs to be determined by their physician based upon their condition. Standard treatment duration for patients with decompensated cirrhosis and

associated conditions can be 12 weeks.

Side Effects

The most common side effects reported in clinical trials were fatigue, itching and headaches.

Cure Rate

Clinical trials report cure rates from Mavyret 8-week treatment are 95% to 100%.

For complete product details see FDA and AbbVie's press release: www.fda.gov and www.abbvie.com

https://news.abbvie.com/news/press-releases/abbvie-receives-fda-approval-mavyret-glecaprevirpibrentasvir-to-shorten-treatment-duration-to-eight-weeks-for-treatment-nave-patients-with-chronic-hepatitis-c-and-compensated-cirrhosis-across-all-genotypes.htm

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