

Generic: glecaprevir and pibrentasvir (FDA approved 08/03/2017)

Company: Abbvie

Agent for: Hepatitis C virus (HCV)

Indications: Treatment for adults with chronic HCV genotype 1-6 infection without cirrhosis and with compensated cirrhosis. Also for treatment of adults with HCV genotype 1 infection who have previously been treated with an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Mechanism of Action: Glecaprevir is a HCV NS3/4A protease inhibitor. HCV NS3/4A is necessary for viral replication. Pibrentasvir is an HCV NS5A inhibitor. HCV NS5A is essential in viral RNA replication and assembly.

COMPARABLE DRUG: Harvoni, Epclusa, Zepatier, Vosevi.

COST PER TREATMENT COURSE (WAC)

INITIAL TREATMENT REGIMEN FOR GENOTYPE 1 W/OUT CIRRHOSIS

EPCLUSA = \$74,760/12WKS

HARVONI = \$94,500/12 WKS

MAVYRET = \$26,376/8 WKS

ZEPATIER = \$54,600-\$72,800/12 – 16 WKS

TREATMENT-EXPERIENCED REGIMENS FOR ALL GENOTYPES

MAVYRET = \$26,376-\$52,752/8 -16 WEEKS

VOSEVI = \$76,760/12 WKS

ADVANTAGES:

- Can cure HCV in many patients in eight weeks whereas other treatments require at least 12 weeks.
- Priced below other approved treatments for HCV.

DISADVANTAGES:

- Cannot be coadministered with atazanavir and rifampin.
- Not recommended for patients with moderate to severe hepatic impairment.
- Interactions with many drugs such as antiarrhythmics, anticoagulants, HIV-antiviral agents, HMG-CoA Reductase Inhibitors and Immunosuppressants.

MOST IMPORTANT RISKS/ADVERSE EVENTS: Patients need to be tested for HBV infection before initiation of treatment. May cause HBV reactivation, which may cause serious liver damage.

MOST COMMON ADVERSE EVENTS: Most common adverse reactions are headache, fatigue and nausea.

USUAL DOSAGE: Three tablets taken orally once daily with food. Treatment duration can range from 8 weeks for patients with no cirrhosis, 12 weeks for patients with compensated cirrhosis or previously have had treatment with an NS3/4A protease inhibitor or up to 16 weeks for patients that previously have had treatment with an NS5A inhibitor or prior treatments but no treatments with neither NS5A inhibitors or NS3/4A protease inhibitors.

PRODUCT: Each tablet contains 100 mg glecaprevir and 40 mg pibrentasvir. Tablets are pink, oblong-shaped, and debossed with "NXT" on one side. Mavyret is supplied in a monthly or 8 week carton. Should be stored below 30°C (86°F) in original container.

COMMENTS: Hepatitis C is a viral disease that causes inflammation in the liver that may lead to diminished function or liver failure. Genotype 1 is the most common type in the U.S. out of the 6 total genotypes. Based on the genotype, different treatments may be recommended. Many people with Hepatitis C have no symptoms but jaundice (yellow eyes or skin), and complications such as bleeding or fluid building in the abdomen may occur. It may lead to liver cancer and cause scars on the liver. Previous treatments focused on strengthening the immune system but more recently approved medications focus on interfering with proteins needed for the virus to grow or spread. In clinical trials, 92-100% of patients who received Mavyret for 8, 12, or 16 weeks had no virus detected in the blood 12 weeks after finishing treatment, suggesting they had been cured.