

Generic: sofosbuvir/ velpatasvir/ voxilaprevir (FDA approved 07/18/2017)

Company: Gilead Sciences

Agent for: Hepatitis C virus (HCV)

Indications: Treatment of adults with chronic hepatitis C without cirrhosis or with compensated cirrhosis who have genotype 1-6 infection and have previously been treated with an NS5A inhibitor or genotype 1a or 3 and have been treated with sofosbuvir without an NS5A inhibitor

Mechanism of Action: Sofosbuvir, velpatasvir and voxilaprevir are DAA agents against the hepatitis C virus. Sofosbuvir inhibits the HCV NS5B RNA polymerase, which is required for viral replication. Velpatasvir inhibits the HCV NS5A protein, which is required for viral replication. Voxilaprevir is a reversible inhibitor of the NS3/4A protease, which is essential for viral replication.

COMPARABLE DRUG: Mavyret

COST PER TREATMENT COURSE (WAC)

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

VOSEVI = \$76,760/12 WKS

ADVANTAGES:

- First Hepatitis C treatment specifically for patients who have had advanced treatment and haven't been cured.
- Effective against all genotypes (1-6) of Hepatitis C

DISADVANTAGES:

- Dosage recommendations cannot be made for patients with severe renal impairments
- Not recommended for patients with moderate or severe hepatic impairments
- Many potential significant drug interactions with other drugs such as acid reducing agents, antiarrhythmics, HMG- CoA Reductase Inhibitors, and Immunosuppressants
- Should not be taken with rifampicin

MOST IMPORTANT RISKS/ADVERSE EVENTS:

Not recommended for coadministration for patients taking amiodarone, may cause serious symptomatic bradycardia. 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 effects were headaches, fatigue, diarrhea, and nausea.

USUAL DOSAGE: One tablet taken orally with food once daily. Treatment duration is approximately 12 weeks.

PRODUCT: Product is in tablet form. Each tablet contains 400mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir. The tablets are beige, capsule-shaped, imprinted with "GSI" on one side and "3" on the other side. 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. Many people with Hepatitis C have no symptoms but jaundice (yellowish eyes or skin), stomach pains, nausea and fatigue 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 two clinical trials for Vosevi, 96-97% of patients who received treatment had no virus detected in blood 12 weeks after finishing treatment, suggesting that the infection had been cured.