MAVYRET

(glecaprevir, pibrentasvir)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Mavyret
- **Generic name:** Glecaprevir, pibrentasvir
- **Pharmacological class:** HCV NS3/4A protease inhibitor + HCV NS5A inhibitor
- **Strength and Formulation:** 100mg/40mg; tabs
- **Manufacturer:** AbbVie
- **How supplied:** Carton—4-Week, 8-Week
- **Legal Classification:** Rx

Mavyret


NDC 0074-2625-28 Rx only
Mavyret™
(glecaprevir and pibrentasvir)
100mg / 40mg
Each tablet contains glecaprevir and pibrentasvir 100mg / 40mg
See Package Insert for full Prescribing Information
DAILY TREATMENT INSTRUCTIONS:
Take all 3 tablets once daily at the same time with food
Take all 3 tablets once daily at the same time with food
Push down on tablets breaking through back side
LIFT HERE

Indications

- Chronic HCV **genotypes 1, 2, 3, 4, 5, or 6** infection without cirrhosis or with compensated cirrhosis
- HCV **genotype 1** infection in adults previously treated with an HCV NS5A inhibitor- or NS3/4A protease inhibitor-containing regimen, but not both

Dosage & Administration

- See full labeling
- Test for HBV infection prior to initiation
- Take with food
- ≥18yrs: 3 tabs once daily
- **Treatment-naive:** treat for 8 weeks (no cirrhosis) or 12 weeks (compensated cirrhosis)

Dosage & Administration

- Treatment-experienced:
  - **Genotype 1:** treat for 16 weeks if previously treated with an NS5A inhibitor (without prior NS3/4A protease inhibitor) or for 12 weeks if previously treated with an NS3/4A protease inhibitor (without prior NS5A inhibitor)

Dosage & Administration

- Treatment-experienced:
  - **Genotypes 1, 2, 4, 5, 6:** treat for 8 weeks (no cirrhosis) or 12 weeks (compensated cirrhosis) if previously treated with regimens containing IFN, PEG-IFN, ribavirin, and/or sofosbuvir, but no prior treatment with an HCV NS3/4A protease inhibitor or NS5A inhibitor

Dosage & Administration

- Treatment-experienced:
  - **Genotype 3:** treat for 16 weeks if previously treated with regimens containing IFN, PEG-IFN, ribavirin, and/or sofosbuvir, but no prior treatment with an HCV NS3/4A protease inhibitor or NS5A inhibitor

Dosage & Administration

- **HCV/HIV-1 co-infected** with compensated liver disease (with or without cirrhosis), **renal impairment** including on hemodialysis: follow same dosage regimen

Considerations for Special Populations

- **Pregnancy:** No adequate human data to establish risk on pregnancy outcomes
- **Nursing mothers:** Consider benefits with potential adverse effects
- **Pediatric:** <18yrs: not established
- **Elderly:** No overall differences in safety or efficacy observed
- **Hepatic impairment:** Moderate (Child-Pugh B): not recommended

Contraindications

- Severe hepatic impairment (Child-Pugh C)
- Concomitant atazanavir or rifampin

Warnings/Precautions

- Risk of **HBV reactivation** in patients coinfected with HCV/HBV
- Test all patients for HBV infection by measuring HBsAg and anti-HBc; if positive serologic evidence, monitor for hepatitis flare or HBV reactivation during and at post-treatment follow-up; treat if clinically indicated

Interactions

- See **Contraindications**
- Concomitant certain immunosuppressants or chemotherapeutic agents: may increase risk of HBV reactivation
- May be antagonized by P-gp/CYP3A inducers (eg, carbamazepine, efavirenz, St. John's wort); concomitant use not recommended

Interactions

- May increase risk of ALT elevations with concomitant ethinyl estradiol-containing drugs (eg, combined oral contraceptives): not recommended
- Concomitant darunavir, lopinavir, ritonavir: not recommended
- Concomitant dabigatran etexilate; refer to its prescribing information for dose modification

Interactions

- Potentiates digoxin (reduce dose by ½); monitor
- Concomitant use may potentiate atorvastatin, lovastatin, simvastatin: not recommended
- May potentiate pravastatin (reduce dose by ½), rosuvastatin (limit max dose at 10mg), fluvastatin, or pitavastatin (use lowest effective dose of both these drugs)
- Patients requiring cyclosporine doses >100mg/day: not recommended

Adverse Reactions

- Headache
- Fatigue
- Nausea
- Diarrhea
- Serum bilirubin elevations
- HBV reactivation

Mechanism of Action

- **Glecaprevir** acts by inhibiting the proteolytic activity of NS3/4A enzymes, thereby preventing the cleavage of the HCV coded polyprotein into mature forms, which results in the inhibition of viral replication
- **Pibrentasvir** inhibits the HCV NS5A enzymes, thereby blocking viral RNA replication and virion assembly

Clinical Studies

- The efficacy of Mavyret in patients with **HCV genotype 1 without cirrhosis** was evaluated in a randomized, open-label trial (N=351)
- After 8 weeks of treatment, 99% of patients achieved SVR12

Clinical Studies

- The efficacy of Mavyret in patients with **HCV genotypes 2, 4, 5, or 6 without cirrhosis** was studied in 3 open-label trials
- Results showed that 98%, 93%, 100%, and 100% of patients, respectively, achieved SVR12 after treatment with Mavyret

Clinical Studies

- Patients with **HCV genotypes 1, 2, 4, 5, or 6 with compensated cirrhosis** were studied in a single-arm, open-label trial (N=146) for 12 weeks
- Results showed that 99% of patients with genotype 1 achieved SVR12, and 100% was seen with genotypes 2, 4, 5, or 6

Clinical Studies

- Mavyret was also evaluated in treatment-naive patients with **HCV genotype 3 without cirrhosis** (SVR12=94.9% for 8 weeks therapy) and with **compensated cirrhosis** (SVR12=98% for 12 weeks)
- In treatment-experienced patients, 95% of patients without cirrhosis achieved SVR and 96% of patients with compensated cirrhosis achieved SVR

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/mavyret/drug/34744/