PATIENTS WITHOUT CIRRHOSIS (GT-1 TO -6)
-6)[1,2†]

✓ **MAVIRET** treatment option for patients with or without renal impairment including patients receiving dialysis.[1]

- No dose adjustment of MAVIRET is required in patients with any degree of renal impairment including patients on dialysis.

No dose adjustment of MAVIRET is required in patients with mild hepatic impairment (Child-Pugh A).[1] MAVIRET is not recommended in patients with moderate hepatic impairment (Child-Pugh B) and is contraindicated in patients with severe hepatic impairment (Child-Pugh C).[1]

GT=genotype; HCV=hepatitis C virus; HBsAg=hepatitis B virus surface antigen; HBc=hepatitis B core antigen
† Comparative clinical significance has not been established.
‡ 3 tablets taken orally at the same time with food, with no regard to fat or calorie content.[1]

Pr MAVIRET®
glecaprevir/pibrentasvir tablets

MAVIRET DEMONSTRATED HIGH SVR_{12} (VIROLOGIC CURE)† RATE

97% (639/657)

Demonstrated 97% SVR_{12} (virologic cure)† rate (95% CI: 95.7, 98.3)[1,5]

Virologic failure occurred at a rate of <1% (6/657)[1]

ACHIEVED IN 8 WEEKS in a subgroup of treatment-naïve, non-cirrhotic GT-1 to -6 adult patients in a pooled analysis of Phase 2 and 3 clinical trials[1,3-5]

The number of patients infected with GT-5 and GT-6 was limited.[1]

EXPEDITION-8

97.9% (274/280)

Demonstrated 97.9% SVR_{12} (virologic cure)† rate with no virologic failures[1]

ACHIEVED IN 8 WEEKS in a single-arm, open-label study of treatment-naïve adult patients with compensated cirrhosis across GT-1, -2, -4 to -6[1]

The number of patients infected with GT-5 and GT-6 was limited.[1]

Please refer to the study parameters at: http://eppendix.com/APS-Abbvie-HCVA

GT=genotype

† SVR_{12} (virologic cure) = Sustained virologic response (SVR_{12}), defined as HCV RNA less than lower limit of quantification (LLOQ) at 12 weeks after the cessation of treatment, was the primary endpoint to determine the HCV cure rate.[1]

MEET KEVIN†

- 28 years old
- Was incarcerated for a 6-month period 5 years ago
- Has chronic hepatitis C (hep C) without cirrhosis and is treatment-naïve
- Has been smoking a pack a day for two years
- Doctor considered treating Kevin with buprenorphine and naloxone, but decided to prescribe methadone (100 mg dv) to treat his opioid addiction[6]

MAVIRET has no observed clinically significant interactions with **methadone**, **buprenorphine** and **naloxone**[1]

Please refer to the Product Monograph for contraindications with dabigatran etexilate, rifampin, atazanavir, ethinyl estradiol, atorvastatin, simvastatin, and interactions with potent P-gp and CYP3A4 inducers, and digoxin, carbamazepine, St. John's wort, darunavir + ritonavir, lopinavir/ritonavir, efavirenz, rilpivirine, lovastatin, pravastatin, rosuvastatin, cyclosporine, tacrolimus and vitamin K antagonists.[1]

CONSIDER MAVIRET FOR YOUR HEP C PATIENTS LIKE KEVIN

† Fictitious patient. May not be representative of the general population.

MEET ANNA†

- 58 years old
- BMI 29
- Has chronic hepatitis C (hep C) without cirrhosis and is treatment-naïve
- Prescribed omeprazole (20 mg bid) for GERD[7]

No dose adjustment is required when MAVIRET is coadministered with **proton-pump inhibitors (omeprazole)**[1†]

Increased gastric pH that may occur in patients treated with omeprazole may reduce absorption of glecaprevir but is not expected to have a clinically significant effect on the efficacy of MAVIRET.[1]

Please refer to the Product Monograph for contraindications with dabigatran etexilate, rifampin, atazanavir, ethinyl estradiol, atorvastatin, simvastatin, and interactions with potent P-gp and CYP3A4 inducers, and digoxin, carbamazepine, St. John's wort, darunavir + ritonavir, lopinavir/ritonavir, efavirenz, rilpivirine, lovastatin, pravastatin, rosuvastatin, cyclosporine, tacrolimus and vitamin K antagonists.[1]

CONSIDER MAVIRET FOR YOUR HEP C PATIENTS LIKE ANNA

BMI=body mass index; bid=twice a day; GERD=symptomatic gastroesophageal reflux disease

† Fictitious patient. May not be representative of the general population.

PrMAVIRET®
glecaprevir/pibrentasvir tablets

8 WEEK TREATMENT

THE ONLY 8-WEEK REGIMEN FOR TREATMENT-NAÏVE PATIENTS WITHOUT CIRRHOSIS (GT-1 TO -6) OR WITH COMPENSATED CIRRHOSIS (GT-1, -2, -4 TO -6)[1,2†]

DEMONSTRATED HIGH SVR_{12} (VIROLOGIC CURE)‡ RATE[1,3-5]

97% SVR_{12} RATE 639/657

- Among the treatment-naïve adult patients without cirrhosis (all genotypes in a subgroup of treatment-naïve, non-cirrhotic adult patients in a pooled analysis of Phase 2 and 3 clinical trials) who received MAVIRET for 8 weeks, the SVR_{12} rate was 97% (639/657) with <1% (6/657) virologic failure rate.

97.9% SVR_{12} RATE 274/280

- Among the treatment-naïve adult patients with compensated cirrhosis (GT-1, -2, -4 to -6) in an open-label, single-arm study who received MAVIRET for 8 weeks, the SVR_{12} rate was 97.9% (274/280) with no virologic failures.
- The number of patients infected with GT-5 and GT-6 was limited across all trials.[1]

DID YOU KNOW?

MAVIRET is taken once daily – 3 tablets taken orally at the same time with food, without regard to fat or calorie content[1§]

Please refer to the study parameters at: http://eppendix.com/APS-Abbvie-HCVA

GT=genotype
† Comparative clinical significance has not been established.
‡ SVR_{12} (virologic cure) = Sustained virologic response (SVR_{12}), defined as HCV RNA less than lower limit of quantification (LLOQ) at 12 weeks after the cessation of treatment, was the primary endpoint to determine the HCV cure rate.[1]
§ MAVIRET tablets should be swallowed whole and not chewed, crushed, or broken.[1]

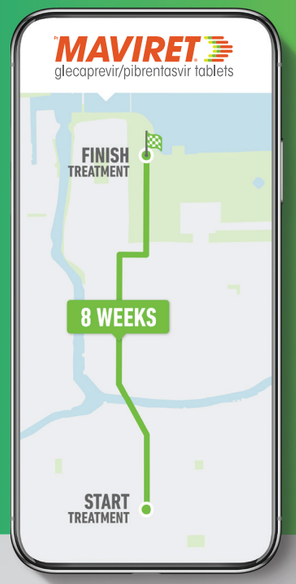
abbvie

Printed in Canada
HCV/1329A - June 2020

abbvie.ca
1-888-703-3006

MEMBER OF INNOVATIVE MEDICINES CANADA | PAAB

PrMAVIRET®
glecaprevir/pibrentasvir tablets



For treatment-naïve patients without cirrhosis (GT-1 to -6) or with compensated cirrhosis (GT-1, -2, -4 to -6).

SHORT 8-WEEK TREATMENT COURSE.[1,2]

SIMPLE ONCE-DAILY DOSING.[1†]

A NEW 8-WEEK TREATMENT DURATION IS NOW AVAILABLE

for your treatment-naïve, compensated cirrhotic patients (genotypes 1, 2, 4 to 6)!

MAVIRET (glecaprevir/pibrentasvir) is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults and adolescent patients 12 to 18 years of age.

MAVIRET is a fixed-dose combination tablet. Please see MAVIRET Product Monograph for complete dosing information.

GT=genotype
† 3 tablets taken orally at the same time with food, with no regard to fat or calorie content. Tablets must be swallowed whole with food: they should not be chewed, crushed, or broken.[1]

PrMAVIRET®
glecaprevir/pibrentasvir tablets

PrMAVIRET®
glecaprevir/pibrentasvir tablets

THE ONLY 8-WEEK REGIMEN FOR TREATMENT-NAÏVE OR WITH COMPENSATED CIRRHOSIS (GT-1, -2, -4 TO

Treatment Durations for Treatment-Naïve Patients‡

Treatment durations depend on HCV genotype, cirrhosis status, and treatment history. Screen all patients for evidence of current or prior HBV infection by measuring HBsAg and anti-HBc before initiating treatment for HCV with MAVIRET.[1]

PrMAVIRET®
glecaprevir/pibrentasvir tablets

Clinical use:

The safety and efficacy of MAVIRET in patients less than 12 years of age have not been established. MAVIRET exposures in HCV-infected patients 12 to 18 years were comparable to those in HCV-infected adults; however, the safety and efficacy of MAVIRET in patients 12 to 18 years infected with HCV genotype 5 or 6 and/or with compensated cirrhosis and/or previously treated with a regimen containing NS5B inhibitor have not been studied.

Contraindications:

- In patients with severe hepatic impairment (Child-Pugh C) as the safety and efficacy have not been established.
- Drugs that are contraindicated with MAVIRET:

Drug Class/ Drug Name	Effect on Concentration	Mechanism of Action	Clinical Comment
ANTICOAGULANTS			
dabigatran etexilate	↑ dabigatran	Inhibition of P-gp by MAVIRET	Coadministration with MAVIRET increased dabigatran concentrations and may increase the risk of bleeding.
ANTIMYCOBACTERIAL			
rifampin	↓ glecaprevir ↓ pibrentasvir	Induction of P-gp, BCRP, and CYP3A by rifampin	Coadministration may significantly decrease concentrations of glecaprevir and pibrentasvir, and lead to loss of therapeutic effect of MAVIRET.
ANTIVIRAL			
atazanavir	↑ glecaprevir ↑ pibrentasvir	Unknown	Risk of ALT elevations when coadministered with MAVIRET.
ETHINYL ESTRADIOL-CONTAINING PRODUCTS			
ethinyl estradiol	↑ ethinyl estradiol	Unknown	Risk of ALT elevations when coadministered with MAVIRET.
HMG-CoA REDUCTASE INHIBITORS			
atorvastatin	↑ atorvastatin	Inhibition of OATP1B1/3, BCRP, P-gp and CYP3A by MAVIRET	Coadministration with MAVIRET increased atorvastatin concentrations and may increase the potential for statin-related myopathy including rhabdomyolysis.
simvastatin	↑ simvastatin	Inhibition of OATP1B1/3 by MAVIRET	Coadministration with MAVIRET increased simvastatin concentrations and may increase the potential for statin-related myopathy including rhabdomyolysis.

Most serious warnings and precautions:

Potential for Hepatitis B virus (HBV) reactivation: Screen all patients for evidence of current or prior HBV infection before initiating MAVIRET therapy. Cases of HBV reactivation, including those resulting in fulminant hepatitis, hepatic failure, and death, have been reported during HCV treatment and/or post-treatment with regimens containing direct-acting HCV antivirals (DAAs) in patients co-infected with HBV.

Other relevant warnings and precautions:

- Should not be coadministered concurrently with other medicinal products containing NS3/4A protease and NS5A inhibitors
- Potent P-gp and CYP3A4 inducers not recommended with MAVIRET; these drugs may significantly decrease the plasma concentration of glecaprevir and pibrentasvir, which may lead to reduced therapeutic effect of MAVIRET or loss of virologic response
- Not recommended in patients with moderate hepatic impairment (Child-Pugh B)
- No human data on the effect of glecaprevir and/or pibrentasvir on fertility are available
- In patients treated with vitamin K antagonist, close monitoring of International Normalised Ratio (INR) is recommended
- HBV screening should be performed in all patients prior to initiation of HCV treatment; patients with positive HBV serology and patients with serologic evidence of resolved HBV infection should be monitored and treated according to current clinical practice guidelines
- Not recommended for patients with rare hereditary problems of galactose intolerance (severe lactase deficiency or glucose-galactose malabsorption)
- Safety and efficacy of MAVIRET have not been established in HCV patients co-infected with Hepatitis B virus (HBV)
- Pregnancy should be avoided while taking MAVIRET
- The number of patients infected with GT-5 and GT-6 was limited

For more information:

Please consult the Product Monograph at abbvie.ca/content/dam/abbviecorp/ca/en/docs/MAVIRET_PM_EN.pdf for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling at 1-888-704-8271.

References: 1. PrMAVIRET® Product Monograph. AbbVie Corporation. March 11, 2020. **2.** Shah H *et al.* The management of chronic hepatitis C: 2018 guideline update from the Canadian Association for the Study of the Liver. *CMAJ* 2018;190:E677-87. **3.** Data on file. Clinical Study Report. Pooled analysis summary. **4.** Data on file. Clinical Study Report. Tables. **5.** Data on file. Pooled analysis Statistical Analysis Plan. **6.** PrSANDOZ METHADONE Product Monograph. Sandoz Canada Inc. December 5, 2019. **7.** PrSANDOZ OMEPRAZOLE Product Monograph. Sandoz Canada Inc. July 31, 2019.