Pibrentasvir PK Fact Sheet

Details

**Generic Name**  
Pibrentasvir

**Trade Name**  
Maviret®, Mavyret®, (co-formulated with glecaprevir)

**Class**  
HCV NS5A inhibitor

**Molecular Weight**  
1113.18

**Structure**

![Structure of Pibrentasvir](image)

Summary of Key Pharmacokinetic Parameters

*Pibrentasvir is available in a fixed-dose combination product with glecaprevir.*

**Linearity/non-linearity**  
Pibrentasvir AUC increased in a greater than dose-proportional manner at doses up to 120 mg, (over 10-fold exposure increase at 120 mg compared to 30 mg), but exhibited linear pharmacokinetics at doses ≥120 mg. The non-linear exposure increase below 120 mg may be related to saturation of efflux transporters.

**Steady state**  
Achieved after 5 days of once daily dosing

**Plasma half-life**  
23-29 h in healthy subjects; 13 h in non-cirrhotic HCV-infected subjects

**Cmax**  
110 (49) ng/mL (geometric mean, %CV), in non-cirrhotic HCV-infected subjects

**C24**  
9.94 (75), 5.33 (48), 6.68 (60) ng/mL (geometric mean, %CV), in healthy White, Han Chinese and Japanese adults, respectively

**AUC**  
1430 (57) ng∙h/mL (geometric mean, %CV), in non-cirrhotic HCV-infected subjects

**Bioavailability**  
Pibrentasvir bioavailability increases 3-fold when given with glecaprevir than when given alone.

**Absorption**  
Compared to fasting, a moderate to high-fat meal increased pibrentasvir exposure by 40-53%.

**Protein Binding**  
>99.9%

**Volume of Distribution**  
Not determined

**CSF:Plasma ratio**  
Not determined

**Semen:Plasma ratio**  
Not determined

**Renal Clearance**  
No renal clearance

**Renal Impairment**  
No dosage adjustment is required in patients with mild, moderate or severe renal impairment, including those on dialysis

**Hepatic Impairment**  
No dose adjustment is required in patients with mild hepatic impairment (Child-Pugh A). Pibrentasvir is not recommended in patients with moderate hepatic impairment (Child Pugh-B) and is contraindicated in patients with severe hepatic impairment (Child-Pugh C).
## Metabolism and Distribution

**Metabolised by**
- Not metabolised - pibrentasvir is eliminated by biliary/faecal excretion

**Inducer of**
- None expected.

**Inhibitor of**
- Inhibitor of P-gp, BCRP, OATP1B1, OATP1B3, BSEP.
- Weak inhibitor of CYP3A, CYP1A2, UGT1A1 (significant interactions are not expected with substrates of these enzymes).
- Significant inhibition of CYP2C9, CYP2C19, CYP2D6, UGT1A6, UGT1A9, UGT1A4, UGT2B7, OCT1, OCT2, OAT1, OAT3, MATE1 or MATE2K are not expected.

**Transported by**
- P-gp, BCRP

## References

**Unless otherwise stated (see below), information is from:**
Maviret Summary of Product Characteristics, AbbVie Ltd.
Mavyret Prescribing Information, AbbVie Inc.
