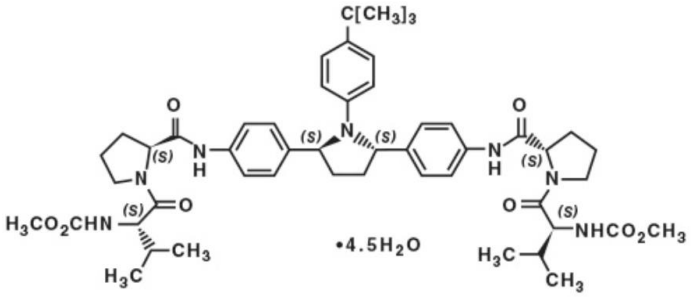
Ombitasvir PK Fact Sheet

Details

Generic Name	Ombitasvir
Trade Name	Viekirax® (coformulated with paritaprevir and ritonavir) Viekira Pak® (coformulated with paritaprevir and ritonavir and copackaged with dasabuvir)
Class	HCV NS5A inhibitor
Molecular Weight	975.2 (hydrate)
Structure	

Summary of Key Pharmacokinetic Parameters

Ombitasvir is available in a fixed-dose combination product with paritaprevir and ritonavir.

Linearity/non-linearity	Ombitasvir exposures increased in a dose proportional manner and accumulation is minimal.
Steady state	Achieved after ~12 days of dosing.
Plasma half life	21-25 h
Cmax	127 (31) ng/ml (geometric mean (%CV); 68 ng/ml (median based population PK analysis). Determined following administration of ombitasvir/paritaprevir/ritonavir 25/150/100 mg once daily with dasabuvir 250 mg twice daily.
Cmin	Not stated
AUC	1420 (36) ng.h/ml (geometric mean (%CV); 1000 ng.h/ml (median based on population PK analysis). Determined following administration of ombitasvir/paritaprevir/ritonavir 25/150/100 mg once daily with dasabuvir 250 mg twice daily.
Bioavailability	~50%
Absorption	Relative to the fasting state, food increased the exposure (AUC) of ombitasvir by 82% with a moderate fat meal (approximately 600 Kcal, 20-30% calories from fat) and by 76% with a high fat meal (approximately 900 Kcal, 60% calories from fat). Ombitasvir should be administered with food.
Protein Binding	~99.9%
Volume of Distribution	50.1 L
CSF:Plasma ratio	Not determined
Semen:Plasma ratio	Not determined
Renal Clearance	~2%
Renal Impairment	No dose adjustment is required for patients with mild, moderate, or severe renal impairment. Administration has not been studied in patients on dialysis.
Hepatic Impairment	No dose adjustment is required in patients with mild hepatic impairment (Child-Pugh A). The European product label does not recommend Viekirax® in patients with moderate hepatic impairment (Child-Pugh B) and contraindicates it in patients with severe hepatic impairment (Child-Pugh C). The US product label contraindicates Viekira Pak® in moderate to severe hepatic impairment (Child-Pugh B and C).

Metabolism and Distribution

Metabolised by	Primarily by amide hydrolysis followed by oxidative metabolism, with only a minor contribution from CYP enzymes.
Inducer of	None expected.
Inhibitor of	UGT1A1 Does not inhibit OAT1 in vivo. Not expected to inhibit OCT1, OCT2, OAT3, MATE1, MATE2K at clinically relevant concentrations.
Transported by	P-gp, BCRP

References

Unless otherwise stated (see below), information is from:
Viekirax® Summary of Product Characteristics, AbbVie Ltd.
Viekira Pak® US Prescribing Information, AbbVie Inc.