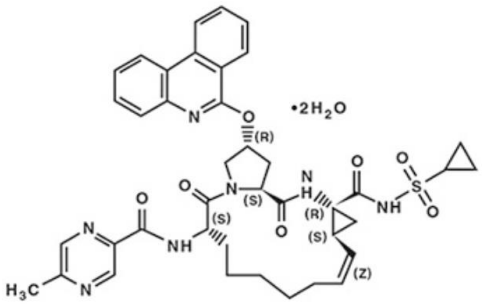
Paritaprevir PK Fact Sheet

Details

Generic Name	Paritaprevir
Trade Name	Viekirax® (coformulated with ombitasvir and ritonavir) Viekira Pak® (coformulated with ombitasvir and ritonavir and copackaged with dasabuvir)
Class	HCV NS3/4A inhibitor
Molecular Weight	801.91 (dihydrate)
Structure	

Summary of Key Pharmacokinetic Parameters

Paritaprevir is available in a fixed-dose combination product with ombitasvir and ritonavir.

Linearity/non-linearity	Paritaprevir exposures increased in a more than dose proportional manner and accumulation is ~1.5-fold.
Steady state	Achieved after ~12 days of dosing.
Plasma half life	~5.5 h
Cmax	1470 (871) ng/ml (geometric mean (%CV); 262 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	6990 (96) ng.h/ml (geometric mean (%CV); 2220 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 211% with a moderate fat meal (approximately 600 Kcal, 20-30% calories from fat) and by 180% with a high fat meal (approximately 900 Kcal, 60% calories from fat). Paritaprevir should be administered with food.
Protein Binding	~97-98.6%
Volume of Distribution	16.7 L
CSF:Plasma ratio	Not determined
Semen:Plasma ratio	Not determined
Renal Clearance	~9%
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	CYP3A4, CYP3A5 (minor)
Inducer of	None expected.
Inhibitor of	UGT1A1, OATP1B1, OATP1B3, OATP2B1, BCRP, P-gp Does not inhibit OAT1 in vivo. Not expected to inhibit OCT1, OCT2, OAT3, MATE1, MATE2K at clinically relevant concentrations.
Transported by	P-gp, BCRP, OATP1B1, OATP1B3

References

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