

Voxilaprevir PK Fact Sheet

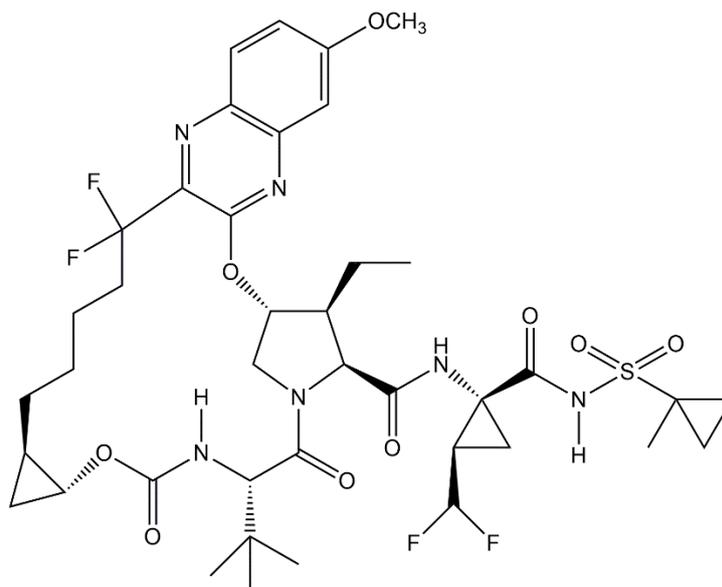
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Details

Generic Name	Voxilaprevir
Trade Name	Vosevi® (co-formulated with sofosbuvir and velpatasvir)
Class	NS3 protease inhibitor
Molecular Weight	868.9
Structure	



Summary of Key Pharmacokinetic Parameters

Linearity/non-linearity	AUC increases in a greater than dose-proportional manner over the dose range of 100 to 900 mg.
Steady state	Not reported.
Plasma half-life	~33 h
C _{max}	192 ng/mL (in HCV infected patients).
C _{min}	5.7 (44.9) ng/mL (mean, %CV). ¹
AUC	2577 ng·hr/mL (in HCV infected patients).
Bioavailability	Not reported.
Absorption	AUC and C _{max} increased by 112-435% and 147-680%, respectively, when voxilaprevir was taken with food.
Protein Binding	>99%
Volume of Distribution	Not reported.
CSF:Plasma ratio	Not reported.
Semen:Plasma ratio	Not reported.
Renal Clearance	Not excreted in urine.
Renal Impairment	No dose adjustment is required for patients with mild or moderate renal impairment. Safety data are limited patients with severe renal impairment or end-stage renal disease requiring haemodialysis. Vosevi can be used in these patients with no dose adjustment when no other treatment options are available.

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Hepatic Impairment No dose adjustment is required for patients with mild hepatic impairment (Child-Pugh A). Voxilaprevir is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C)

Metabolism and Distribution

<i>Metabolised by</i>	CYP3A4
<i>Inducer of</i>	None expected
<i>Inhibitor of</i>	BCRP, OATP1B1/3, P-gp
<i>Transported by</i>	BCRP, OATP1B1/3, P-gp

References

Unless otherwise stated (see below), information is from:

Vosevi Summary of Product Characteristics, Gilead Sciences Ltd.

Vosevi Prescribing Information, Gilead Sciences Inc.

1. P0861: evaluation of the pan-genotypic HCV NS3/4A protease inhibitor GS-9857 in healthy volunteers. Kirby B, Yang J, Yang C et al. J Hepatol, 2011, 62: S663.