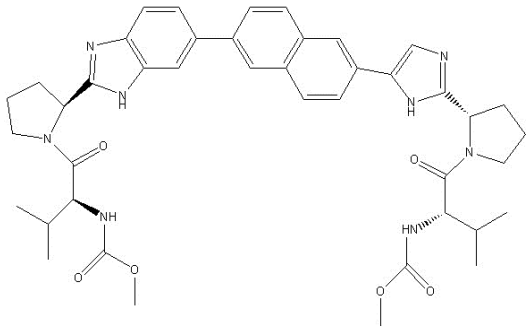
Ravidasvir PK Fact Sheet

Details

Generic Name	Ravidasvir
Trade Name	Ravida®
Class	HCV NS5A inhibitor
Molecular Weight	762.9
Structure	

Summary of Key Pharmacokinetic Parameters

Linearity/non-linearity	At the dose ranges tested in volunteers (80-320 mg) and HCV patients (40-240 mg), the relationship between the dose and the AUC and C_{max} was linear.
Steady state	Steady state was achieved by day 7 of daily oral dosing with 200 mg ravidasvir in healthy volunteers.[1]
Plasma half life	7.26 h (100 mg), 7.37 h (200 mg), 7.39 h (300 mg), oral, healthy volunteers.[1]
Cmax	2,540 ng/mL
Ctrough	190 ng/mL
AUC	19,920 h·ng/mL
Bioavailability	Not reported.
Absorption	Relative to fasting conditions, ravidasvir C_{max} was reduced when ravidasvir was taken with food, however the relative bioavailability was unchanged (fed/fasted 103.4%). Ravidasvir can be taken with or without food.
Protein Binding	Highly bound, estimated unbound fraction 1.9%.
Volume of Distribution	Approximately 100 L.
CSF:Plasma ratio	Not determined.
Semen:Plasma ratio	Not determined.
Renal Clearance	Negligible.
Renal Impairment	No studies have been conducted in patients with renal impairment or end stage renal disease. Treatment with ravidasvir should be guided by assessment of the potential risks and benefits for the individual patient.
Hepatic Impairment	No dose adjustment of ravidasvir is required for patients with mild hepatic impairment (CPT Class A). Safety and efficacy of ravidasvir have been assessed in patients compensated cirrhosis, but not in patients with decompensated cirrhosis. The safety and efficacy have not been assessed in patients with severe hepatic impairment (CPT Class C).

Metabolism and Distribution

Metabolised by	Negligible, mono-oxidation.
Inducer of	None reported.
Inhibitor of	BCRP, OATP1B1/3 (weak), CYP3A4 (weak), CYP2C19 (weak), UGT1A1 (weak).
Transported by	P-gp.

References

Unless otherwise stated (see below), information is from:
Ravida® Prescribing Information, Doppel Farmaceutici s.r.l., June 2021.

1. Pharmacokinetics, Safety, and Tolerability of Ravidasvir, with and without Danoprevir/Ritonavir, in Healthy Subjects. Wu G, Zhou H, Wu J, et al. Antimicrob Agents Chemother, 2021;65(10): e0060021.