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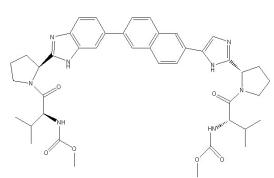
Ravidasvir PK Fact Sheet

Revised September 2023

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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. $^{\rm 1}$ |
| Plasma half life | 7.26 h (100 mg), 7.37 h (200 mg), 7.39 h (300 mg), oral, healthy volunteers.1 |
| Стах | 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). |
| | |

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| 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.

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