Dasabuvir PK Fact Sheet

Details

Generic Name: Dasabuvir
Trade Name: Exviera®, Viekira Pak® (copackaged with ombitasvir/paritaprevir/ritonavir)
Class: HCV non-nucleoside NS5B palm polymerase inhibitor
Molecular Weight: 533.57 (salt, hydrate)

Structure:

Summary of Key Pharmacokinetic Parameters

Dasabuvir must always be administered together with ombitasvir/paritaprevir/ritonavir. It is available as a single agent or copackaged with ombitasvir/paritaprevir/ritonavir.

Linearity/non-linearity: Dasabuvir exposures increased in a dose proportional manner and accumulation is minimal.

Steady state: Achieved after ~12 days of dosing.

Plasma half life: 5.5-6.0 h

Cmax: 1030 (31) ng/ml (geometric mean (%CV); 667 ng/ml (median based population PK analysis). Determined following administration of dasabuvir 250 mg twice daily with ombitasvir/paritaprevir/ritonavir 25/150/100 mg once daily.

Cmin: Not stated

AUC: 6840 (32) ng.h/ml (geometric mean (%CV); 3240 ng.h/ml (median based on population PK analysis). Determined following administration of dasabuvir 250 mg twice daily with ombitasvir/paritaprevir/ritonavir 25/150/100 mg once daily.

Bioavailability: ~70%

Absorption: Relative to the fasting state, food increased the exposure (AUC) of ombitasvir by 30% with a moderate fat meal (approximately 600 Kcal, 20-30% calories from fat) and by 22% with a high fat meal (approximately 900 Kcal, 60% calories from fat). Dasabuvir should be administered with food.

Protein Binding: >99.5%

Volume of Distribution: 149 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). Dasabuvir is contraindicated in moderate to severe hepatic impairment (Child-Pugh B and C).
## Metabolism and Distribution

**Metabolised by**
CYP2C8, CYP3A4 (minor)

**Inducer of**
None expected.

**Inhibitor of**
- UGT1A1 (in vivo), BCRP (in vivo), P-gp (in vitro).
- Inhibits UGT1A4, UGT1A6 and intestinal UGT2B7 in vitro at in vivo relevant concentrations.
- Does not inhibit OCT1 in vivo. Not expected to inhibit OCT2, OAT3, MATE1, MATE2K at clinically relevant concentrations.

**Transported by**
P-gp, BCRP.

## References

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