**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**  
396 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). The European product label does not recommend dasabuvir 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**
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, 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.*