**Voxilaprevir PK Fact Sheet**

**Details**

- **Generic Name**: Voxilaprevir
- **Trade Name**: Vosevi® (co-formulated with sofosbuvir and velpatasvir)
- **Class**: HCV NS3/4A inhibitor
- **Molecular Weight**: 868.9

**Structure**

![Voxilaprevir Structure](image)

**Summary of Key Pharmacokinetic Parameters**

**Voxilaprevir is available in a fixed-dose combination product with sofosbuvir and velpatasvir.**

- **Linearity/non-linearity**: Voxilaprevir AUC (studied under fed conditions) increases in a greater than dose-proportional manner over the dose range of 100 to 900 mg.

- **Steady state**: Achieved after approximately 7 days of once daily dosing \(^1\)

- **Plasma half life**: ~33h

- **Cmax**: 192 (85.8) ng/ml (mean, %CV, based on population PK modelling)

- **Ctrough**: 47 (82.0) ng/ml (mean, %CV, based on population PK modelling)

- **AUC**: 2577 (73.7) ng.h/ml (mean, %CV, based on population PK modelling)

- **Bioavailability**: Not determined

- **Absorption**: Relative to fasting conditions, administration of voxilaprevir with food increase voxilaprevir AUC and Cmax by 112-435% and 147-680%, respectively. Vosevi should be 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. The safety and efficacy have not been assessed in patients with severe renal impairment or end-stage renal disease requiring haemodialysis

- **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

<table>
<thead>
<tr>
<th>Metabolised by</th>
<th>CYP3A4, CYP1A2, CYP2C8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inducer of</td>
<td>None expected.</td>
</tr>
<tr>
<td></td>
<td>Does not induce metabolising enzymes or transporters via the AhR or PXR receptors (^1) (e.g. CYPs 1A1, 1A2, 1B1, 2A6, 2B6, 2C9, 3A4; UGT1A1; BCRP, MDR1; MRP2, OATP2)</td>
</tr>
<tr>
<td>Inhibitor of</td>
<td>Inhibits P-gp, BCRP, OATP1B1, OATP1B3</td>
</tr>
<tr>
<td></td>
<td>At clinically relevant concentrations, voxilaprevir is not an inhibitor of hepatic transporters OCT1, renal transporters OCT2, OAT1, OAT3 or MATE1, or CYP or UGT1A1 enzymes.</td>
</tr>
<tr>
<td>Transported by</td>
<td>P-gp, BCRP, OATP1B1, OATP1B3</td>
</tr>
</tbody>
</table>

## References

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

- Vosevi® Summary of Product Characteristics, Gilead Sciences Ltd.
- Vosevi® US Prescribing Information, Gilead Sciences Inc.