Sofosbuvir/Velpatasvir

**COMPOSITION**

Sofosbuvir Tablet: Each light green tablet contains Sofosbuvir 300 mg and Velpatasvir 100 mg.

**PHARMACOLOGICAL INFORMATION**

**Therapeutic class:** Antiviral agent.

**PHARMACOLOGICAL ACTION**

Mechanism of Action:

Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication. Sofosbuvir is a nucleos(t)ide analog that is not converted into an active metabolite for the inhibition of the enzyme. Velpatasvir is an HCV NS5A protein inhibitor that is not converted into an active metabolite.

**Interactions with Sofosbuvir and Velpatasvir**

The pharmacokinetic properties of the components of Sofosbuvir/Velpatasvir are provided in Table 1.

**Table 1: Pharmacokinetic properties of the Components of Sofosbuvir/Velpatasvir**

<table>
<thead>
<tr>
<th>Component</th>
<th>Absorption</th>
<th>Distribution</th>
<th>Metabolism</th>
<th>Excretion</th>
<th>Elimination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir</td>
<td>Poor (4.1%)</td>
<td>Moderate (61-65%)</td>
<td>Partially reversible (61-65%)</td>
<td>76%</td>
<td>98%</td>
</tr>
<tr>
<td>Velpatasvir</td>
<td>Poor (4.1%)</td>
<td>Moderate (61-65%)</td>
<td>Partially reversible (61-65%)</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Specific Populations**

Pediatric Patients

The pharmacokinetics of Sofosbuvir or Velpatasvir in pediatric patients has not been established.

Geriatric Patients

Population pharmacokinetic analysis in HCV-infected subjects showed that within the age range (18 to 82 years) analyzed, age did not have a clinically relevant effect on the exposure to Sofosbuvir or Velpatasvir.

Patients with Hepatic Impairment

The pharmacokinetics of Sofosbuvir were studied in HCV-negative subjects with mild (eGFR between 60 to less than 90 mL/min/1.73 m²), moderate (eGFR between 30 to less than 60 mL/min/1.73 m²), and severe renal impairment (eGFR less than 30 mL/min/1.73 m²). No clinically relevant differences were observed between healthy subjects and subjects with renal impairment.

Patient population pharmacokinetic analysis in HCV-infected subjects indicated that cirrhosis (including decompensated cirrhosis) had no clinically relevant effect on the exposure of Velpatasvir.

**ADVERSE REACTIONS**

The most common adverse events observed with Sofosbuvir and Velpatasvir combination were fatigue, nausea, headache, anorexia, insomnia, pruritus, muscle spasm, and dysphoria. There were some rare adverse events including reduced hemoglobin level, reduced lymphocyte count, reduced neutrophil count, and increased alanine aminotransferase.

**CONTRAINdications**

Sofosbuvir and Velpatasvir combination regimen is contraindicated in patients for whom Ribavirin is contraindicated. Refer to the Ribavirin prescribing information for a list of contraindications for Ribavirin.

**DRUG INTERACTIONS**

Potential for Other Drugs to Affect Sofosbuvir/Velpatasvir

Sofosbuvir and Velpatasvir are substrates of drug transporters P-gp and BCRP when GS-331007 is coadministered with Sofosbuvir/Velpatasvir. Drugs that induce or inhibit the activity of drug transporters P-gp and BCRP may affect the pharmacokinetics of Sofosbuvir and Velpatasvir. The concomitant use of Sofosbuvir/Velpatasvir with P-gp and/or BCRP inhibitors or inducers may affect the pharmacokinetics of Sofosbuvir or Velpatasvir. Serious symptomatic Bradycardia developed when Sofosbuvir was coadministered with Amiodarone and another HCV Direct Acting Antiviral.

**REFERENCES**

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