**Simeprevir (Olysio)**

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**Drug Summary**

When first introduced, simeprevir provided an excellent alternative to the older first-generation NS3/4A protease inhibitors (boceprevir and telaprevir) for the treatment of patients with genotype 1 HCV. Simeprevir is convenient (once-daily dosing), well-tolerated, and has less extensive drug-drug interactions than the first-generation protease inhibitors. Simeprevir is now infrequently used for the treatment of hepatitis C due to the availability of more effective and better tolerated direct-acting antiviral agents.

**Class and Mechanism**

Simeprevir is a NS3/4A hepatitis C virus (HCV) protease inhibitor. Simeprevir is a macrocyclic compound that non-covalently binds to and inhibits the NS3/4A HCV protease, a protein that is responsible for cleaving and processing the HCV-encoded polyprotein, a critical step in HCV viral life cycle. Simeprevir is considered a second generation HCV protease inhibitor because of the enhanced binding affinity and specificity to NS3/4A when compared with the first-generation protease inhibitors with linear structure.

**Manufacturer for United States**

Simeprevir is manufactured as Olysio (oh li see oh) by Janssen Research & Development (Figure 1) and (Figure 2). Simeprevir was jointly developed by Janssen Research & Development and Medivir AB, originally known as compound TMC-435. Janssen has a collaborative agreement with Idenix Pharmaceuticals for the clinical development of combination oral direct acting therapies for the treatment of hepatitis C infection and simeprevir is among the drugs included in this agreement.
Cost and Medication Access

The wholesale acquisition cost (WAC) for simeprevir is $790 per 150 mg capsule. The cost for a 28-days supply of simeprevir is $22,120 and a 12-week supply is $66,360. Thus, a typical 12-week treatment course of simeprevir when used with a total of 24-weeks of peginterferon plus ribavirin will cost approximately $85,000. A 12-week course of simeprevir plus sofosbuvir costs approximately $150,000. Janssen has a simeprevir patient assistance program for treatment eligible patients with hepatitis C who are not able to obtain access to simeprevir. Medical providers and patients can learn more about this program by visiting the Janssen Prescription Assistance Program website or by calling 1-855-565-9746.

Adverse Effects

The most common adverse effects attributable to simeprevir are rash (including a potentially serious photosensitivity reaction), pruritus, and nausea.

- The photosensitivity reaction that can occur with simeprevir most often has an onset during the first 4 weeks of therapy, but can develop at any time on treatment (Figure 3).
- Patients taking simeprevir should limit sun exposure, use protective sun exposure measures, and avoid use of any tanning device.
- If a photosensitivity rash does occur while taking simeprevir, discontinuation of simeprevir should be considered and the patient should have close monitoring until the rash has resolved.
- Rash not related to photosensitivity can also occur and similar to the photosensitivity rash most often develops during the first 4 weeks of therapy.
- Simeprevir contains a sulfonamide moiety, but insufficient data exist to know the risk of taking simeprevir in persons with a prior "sulfa allergy".
- Patients taking simeprevir may experience transient and increases in serum bilirubin levels that peak at week 2 of treatment that are typically mild in severity and not associated with elevated hepatic aminotransferase levels.
- Simeprevir is pregnancy category C.

Key Drug Interactions

For complete information on simeprevir-related drug interactions, see the Drug Interactions section in the Simeprevir (Olysio) Prescribing Information.