

Olysio® (simeprevir) – Drug discontinuation

- <u>Janssen announced</u> the discontinuation of <u>Olysio (simeprevir)</u> due to a significant decline in utilization and the availability of effective therapies, such as pangenotypic combination regimens, which address the current medical need in treating hepatitis C virus (HCV) infection.
 - The discontinuation was not due to any safety, efficacy or quality issues.
 - Moreover, Janssen will voluntary withdraw the New Drug Application for Olysio in the U.S. and product will no longer be available, effective May 25, 2018.
- Olysio, an HCV NS3/4A protease inhibitor, is indicated for the treatment of adults with chronic HCV infection in combination with <u>Sovaldi®</u> (sofosbuvir) in patients with HCV genotype 1 without cirrhosis or with compensated cirrhosis and in combination with peginterferon alfa (<u>Pegasys®</u>, <u>Peg-Intron®</u>) and <u>ribavirin</u> in patients with HCV genotype 1 or 4 without cirrhosis or with compensated cirrhosis.
 - Incivek[®] (telaprevir) and <u>Victrelis[®] (boceprevir)</u> were previously approved HCV NS3/4A protease inhibitors that were discontinued in 2014 and 2015, respectively, for business reasons.
- Healthcare professionals are advised not to initiate new patients on Olysio.
- Patients who are currently taking Olysio should complete their course of therapy in consultation with their healthcare provider. For patients who are unable to complete a full course of therapy, Janssen recommends healthcare providers refer to local guidelines on the treatment of hepatitis C.
- Examples of currently available pangenotypic combination regimens indicated to treat HCV include <u>Epclusa®</u> (sofosbuvir/velpatasvir), <u>Mavyret™</u> (glecaprevir/pibrentasvir), and <u>Vosevi®</u> (sofosbuvir/velpatasvir/voxilaprevir). Refer to individual drug labels for indication information.
- For assistance or questions about the discontinuation of Olysio, contact Janssen at 1-800-526-7736.



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