

Mylan launches generic Hepatitis C drug

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Mylan NV announced that its subsidiary, Mylan Pharmaceuticals Private Limited, has launched generic Harvoni (Ledipasvir 90 mg/Sofosbuvir 400 mg) tablets under the brand name MyHep LVIR in India.

Mylan launches generic Harvoni (Ledipasvir/Sofosbuvir) under the brand name MyHep LVIR in the country.

The Ledipasvir/Sofosbuvir combination is indicated for the treatment of Hepatitis C infection and offers a simplified Hepatitis C treatment regimen that eliminates the need for interferon and ribavirin. The product also is a single-tablet regimen and requires a therapy course of just 12 weeks. Harvoni has exhibited high cure rates and a tolerable side effect profile across a range of patient populations.

Mylan president Mr Rajiv Malik said, "Mylan recognizes the urgent need to expand access to high quality, affordable Hepatitis C treatment options in India, where roughly 12 million people are infected with the virus. MyHep LVIR is an important addition to our growing Hepato Care segment in India that gives us the opportunity to offer patients the potential to be cured through a transformative and simplified single tablet, once-daily treatment regimen. Moreover, consistent with our commitment to create better health for a better world, we are introducing various educational initiatives in India to raise awareness of the disease and its treatment options."

The launch of MyHep LVIR follows the successful launch of generic Sofosbuvir in India under the brand name MyHep in April 2015. In September 2014, Mylan entered into a licensing and technology transfer agreement with Gilead granting Mylan the non-exclusive rights to manufacture and distribute generic Sofosbuvir and Ledipasvir/Sofosbuvir tablets in 101 developing countries, including India.

Mylan also entered into an agreement with Gilead in February 2015 as the exclusive distributor of Gilead's branded Sovaldi (Sofosbuvir 400 mg) and Harvoni tablets in India. Mylan launched Sovaldi in India in May 2015.