

DCGI nod for Natco's hepatitis C drug

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Natco Pharma has announced that it has received approval for the generic version of ledipasvir+sofosbuvir combination from Drugs Controller General of India (DCGI). NATCO plans to launch this combination drug immediately, under its brand name Hecpinat LP, and through its strategic partners in India.

Ledipasvir+Sofosbuvir is a two-drug fixed-dose combination product that contains 90 mg of ledipasvir and 400 mg of sofosbuvir in a single tablet, and sold globally by Gilead Sciences, under its brand HARVONI. It is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults. This single-tablet regimen is the first of its kind to offer significantly higher cure rates in Genotype-1 CHC infection compared to conventional therapies.

NATCO will price its generic medicine, Hecpinat LP, at an MRP of Rs 25,000/- for a bottle of 28 tablets. NATCO was the first licensed company to launch the generic version of this combination drug earlier in Nepal. NATCO had signed a non-exclusive licensing agreement with Gilead Sciences earlier in 2015, to manufacture and sell generic versions of its chronic hepatitis C medicines, including generic version of HARVONI, in 100 other developing countries in addition to India.