

SOFOCRUZ LP

To be sold by retail on prescription of Hepatologist only.

Abbreviated Prescribing information for **SOFOCRUZ LP (Ledipasvir & Sofosbuvir Tablets 90 mg + 400 mgs)** [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Ledipasvir is a HCV inhibitor targeting the HCV NS5A protein, which is essential for both RNA replication and the assembly of HCV virions. Sofosbuvir is a pan-genotypic inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication.

INDICATIONS: For the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.

DOSAGE AND ADMINISTRATION: The recommended dose of Sofocruz LP is one tablet once daily with or without food.

CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients. Co-administration with rosuvastatin or St. John's wort (*Hypericum perforatum*).

PRECAUTIONS Sofocruz LP should not be administered concomitantly with other medicinal products containing sofosbuvir. Cases of severe bradycardia and heart block have been observed when Sofocruz LP is used with concomitant amiodarone with or without other drugs that lower heart rate. P-glycoprotein (P-gp) inducers (e.g. rifampicin, carbamazepine and phenytoin) may significantly decrease ledipasvir and sofosbuvir plasma concentration which may lead to reduced therapeutic effect of Sofocruz LP, HMG-CoA reductase inhibitors (statins) can significantly increase the concentration of the statin, which increases the risk of myopathy and rhabdomyolysis.

DRUG INTERACTIONS: Amiodarone, digoxin, dabigatran etexilate, carbamazepine, phenytoin, phenobarbital, rifampicin, rifabutin rifapentine, carbazepine and simeprevir.

ADVERSE REACTIONS: Headache, fatigue, decreases in haemoglobin, Cases of severe bradycardia and heart block have been observed when Sofocruz LP is used with concomitant amiodarone and/or other drugs that lower heart rate.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)