

SOFOCRUZ

To be sold by retail on prescription of hepatologist only

Abbreviated Prescribing information for **Sofocruz** [Sofosbuvir Tablets 400mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Sofosbuvir is a direct-acting antiviral agent against the hepatitis C virus

INDICATION: In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.

DOSAGE AND ADMINISTRATION: The recommended dose of sofosbuvir is one 400 mg tablet, taken orally, once daily with or without food. It is taken with combination therapy and has specific treatment duration such as Sofosbuvir + ribavirin + peginterferon alfa for 12 weeks, Sofosbuvir + ribavirin for 24 weeks, Sofosbuvir + ribavirin + peginterferon alfa for 12 weeks.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients Sofosbuvir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

WARNINGS & PRECAUTIONS: Postmarketing cases of symptomatic bradycardia and cases requiring pacemaker intervention have been reported when amiodarone is coadministered with sofosbuvir in combination with an investigational agent (NS5A inhibitor) or simeprevir.

DRUG INTERACTIONS: Amiodarone, carbamazepine phenytoin Phenobarbital, oxcarbazepine, rifabutin , rifampin , Modafinil ,P-gp inducers ,rifapentine and tipranavir/ritonavir.

ADVERSE REACTIONS: Fatigue, headache, vision blurred , alopecia, dry skin , blood bilirubin increased , chills, fatigue, influenza-like illness,irritability, pain, pyrexia nausea, insomnia, pruritus, anemia, asthenia, rash, decreased appetite, chills, influenza, like illness, pyrexia, diarrhea, neutropenia, pancytopenia (particularly in subjects receiving concomitant pegylated interferon), severe depression (particularly in subjects with pre-existing history of psychiatric illness), including suicidal ideation and suicide, changes in selected hematological parameters, cardiac disorders serious symptomatic bradycardia myalgia and irritability.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)