

# Hopetavir™

Sofosbuvir 400 mg tablet

## Presentation

Hopetavir™: Each tablet contains Sofosbuvir INN 400 mg.

## Description

Sofosbuvir is a direct-acting antiviral agent against the hepatitis C virus. It is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication.

## Indications and Uses

Sofosbuvir is indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.

- Sofosbuvir efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection

## Dosage and Administration

- One 400 mg tablet taken once daily with or without food
- Should be used in combination with Ribavirin or in combination with Pegylated Interferon and Ribavirin for the treatment of CHC. Recommended combination therapy:

HCV Mono-infected and HCV/HIV-1 Co-infected	Treatment	Duration
Genotype 1 or 4	Sofosbuvir + Peginterferon alfa + Ribavirin	12 weeks
Genotype 2	Sofosbuvir + Ribavirin	12 weeks
Genotype 3	Sofosbuvir + Ribavirin	24 weeks

- Sofosbuvir in combination with Ribavirin for 24 weeks can be considered for CHC patients with genotype 1 infection who are Interferon ineligible
- Should be used in combination with Ribavirin for treatment of CHC in patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation whichever occurs first
- A dose recommendation cannot be made for patients with severe renal impairment or end stage renal disease

## Side-effects

The most common adverse events observed with Sofosbuvir in combination with Ribavirin were fatigue and headache. The most common adverse events observed with Sofosbuvir in combination with Peginterferon alfa and Ribavirin were fatigue, headache, nausea, insomnia and anemia.

## Contraindications

When Sofosbuvir is used in combination with Ribavirin or Peginterferon alfa/Ribavirin, the contraindications applicable to those agents are applicable to combination therapies. 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.

## Precaution

Pregnancy: Ribavirin may cause birth defects and fetal death and animal studies have shown interferons have abortifacient effects; avoid pregnancy in female patients and female partners of male patients. Patients must have a negative pregnancy test prior to initiating therapy, use at least 2 effective methods of contraception and have monthly pregnancy tests.

## Pregnancy and Lactation

*Pregnancy Category X: Use with Ribavirin or Peginterferon alfa/Ribavirin*

Extreme caution must be taken to avoid pregnancy in female patients and female partners of male patients while taking this combination. Women of childbearing potential and their male partners should not receive Ribavirin unless they are using two forms of effective contraception during treatment with Ribavirin and for 6 months after treatment has concluded

*Pregnancy Category B: Sofosbuvir monotherapy*

There are no adequate and well-controlled studies with Sofosbuvir in pregnant women.

Lactation: It is not known whether Sofosbuvir and its metabolites are present in human breast milk. Because of the potential for adverse reactions from the drug in nursing infants, a decision must be made whether to discontinue nursing or discontinue treatment with Ribavirin-containing regimens, taking into account the importance of the therapy to the mother.

## Pediatric Use

Safety and effectiveness of Sofosbuvir in children less than 18 years of age have not been established.

## Drug Interactions

Drugs that are potent intestinal P-gp inducers (e.g., rifampin, St. John's wort) may alter the concentrations of Sofosbuvir.

## Commercial Pack

Hopetavir™: Each box contains 1 blister strip of 6 tablets.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Dhaka, Bangladesh

V.N.01  
HPT