

SOVENTA[®]

Sofosbuvir INN
Film Coated Tablet

DESCRIPTION

Soventa[®] Tablet: is a preparation of Sofosbuvir. Sofosbuvir is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Sofosbuvir's efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infections, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.

INDICATIONS

Chronic hepatitis C (CHC) infection

DOSAGE AND ADMINISTRATION

- ▶ The recommended dose of Sofosbuvir is one 400 mg tablet once daily orally with or without food
- ▶ Sofosbuvir should be used in combination with Ribavirin or in combination with pegylated interferon and Ribavirin for the treatment of CHC in adults

HCV Mono-infected and HCV/HIV-1 Co-infected	Treatment	Duration
Genotype 1 or 4	Sofosbuvir + peg-interferon 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

CONTRAINDICATIONS

► When Sofosbuvir is used in combination with Ribavirin or peg-interferon alfa/Ribavirin, the contraindications applicable to those agents are applicable to combination therapies

WARNING AND PRECAUTIONS

► Serious Symptomatic Bradycardia when co-administered with Amiodarone and Another HCV Direct Acting Antiviral

► No dose recommendation can be given for patients with severe renal impairment (estimated Glomerular Filtration Rate (eGFR) <30 mL/min/1.73m²) or with end stage renal disease (ESRD) due to higher exposures (up to 20-fold) of the predominant Sofosbuvir metabolite

USE IN PREGNANCY AND LACTATION

Sofosbuvir combination treatment with Ribavirin or peg-interferon alfa/Ribavirin is contraindicated in women who are pregnant or may become pregnant because of the risks for birth defects and fetal death associated with Ribavirin.

SIDE EFFECTS

- Fatigue
- Headache
- Nausea
- Insomnia
- Anemia

PHARMACEUTICAL PRECAUTION

Store below 25 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Soventa[®] Tablet: Box containing 1 strip of 6 tablets. Each tablet contains Sofosbuvir INN 400 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LTD.

GAZIPUR, BANGLADESH.

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