

Composition : Sofosbuvir 400 mg.

Indications : Sofosbuvir is used with other antiviral medications such as Ribavirin & Peginterferon to treat Chronic Hepatitis C (CHC) infections. Its 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.

Dosage & Administration : (Dosage for Adults) : 400 mg Tablet is recommended orally once daily with or without food. The Recommended regimen & treatment duration for Sofosbuvir in the combination therapy are given below:

| Characteristics□ | Treatment□ | Duration |
|---|--|-----------|
| Patients with genotype 1 or 4 CHC□ □ | Sofosbuvir + Peginterferon□ alfa + Ribavirin. | 12weeks. |
| Patients with genotype 2 CHC□ | Sofosbuvir + Ribavirin.□ | 12 weeks. |
| Patients with genotype 3 CHC□ | Sofosbuvir + Ribavirin.□ | 24 weeks. |

Or, as directed by the registered physicians.

Side effects : The most common side effects are: i) For Sofosbuvir + Ribavirin Combination Therapy: Fatigue and headache. ii) For Sofosbuvir + Peginterferon alfa + Ribavirin Combination Therapy: Fatigue, headache, nausea, insomnia and anemia.

Contraindication : When it is used in combination with Peginterferon alfa and/or Ribavirin, all contraindications to Peginterferon alfa and/or Ribavirin also apply to Sofosbuvir combination therapy.

Pregnancy & Lactation : Sofosbuvir should be used only when clearly needed. Ribavirin may cause birth defects or fetal death. Caution should be exercised highly when it is used in combination with Ribavirin or Ribavirin & Peginterferon to avoid pregnancy in female patients & female partners of male patients. It is not known if Sofosbuvir passes into breast milk. Breast-feeding while using

Hopso
Tablet



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Sofosbuvir, in combination with Ribavirin or Peginterferon, is not recommended.

Precaution : Sofosbuvir should be used in combination with Ribavirin or Peginterferon or both. Women of childbearing potential and their male partners should not receive Ribavirin unless they are using two forms of effective contraception during treatment and for 6 months after treatment has concluded. Patients must have a negative pre-pregnancy test prior to initiating therapy and have monthly pregnancy tests.

Drug Interactions : Sofosbuvir should not be used with P-gp inducers (Rifampin or St. John's wort), Carbamazepine, Phenytoin, Phenobarbital, Rifabutin, Rifapentine, Retonavir. Because, these drugs decrease Sofosbuvir plasma concentrations and may lead to reduced its therapeutic effect.

Packing : Hopso : 1 x 7's tablets in blister pack.