Only for the use of Medical Professionals

Sofomax®

Sofosbuvir

Description

Sofomax® is a nucleotide analog used in combination with other drugs for the treatment of hepatitis C virus (HCV) infection. **Sofomax**® inhibits the RNA polymerase that the hepatitis C virus uses to replicate its RNA. **Sofomax**® is used for the treatment of chronic hepatitis C, genotypes 1, 2, 3, and 4. It is also used in combination with the viral NS5a inhibitor Ledipasvir in an interferon-free combination for the treatment of genotype 1 hepatitis C infection. **Sofomax**® is also used in HCV patients with an HIV co-infection.

Indications

Sofomax® is indicated for the treatment of genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen.

Dosage and administration

The recommended dosage of **Sofomax**® is one 400 mg tablet taken orally once daily with or without food.

Administer **Sofomax**® in combination with Ribavirin or in combination with Pegylated interferon and Ribavirin for the treatment of HCV. The recommended treatment regimen and duration for **Sofomax**® combination therapy is below -

Patient Population	Treatment Regimen	Duration
Genotype 1 or 4	**Sofomax**® + PEG interferon Alfa + Ribavirin	12 weeks
Genotype 2	**Sofomax**® + Ribavirin	12 weeks
Genotype 3	**Sofomax**® + Ribavirin	24 weeks

Use in pediatric patients

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

Use in pregnancy

Pregnancy category of Sofosbuvir: B

Use in geriatric

No dosage adjustment of **Sofomax**® is warranted in geriatric patients.

Use in renal impairment patients

No dosage adjustment of **Sofomax**® is required for patients with mild or moderate renal impairment. The safety and efficacy of **Sofomax**® have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73m^2) or ESRD requiring hemodialysis. No dosage recommendation can be given for patients with severe renal impairment or ESRD.

Use in hepatic impairment patients

No dosage adjustment of **Sofomax**® is required for patients with mild, moderate or severe hepatic impairment. Safety and efficacy of **Sofomax**® have not been established in patients with decompensated cirrhosis.

Side effects

The most common side effects of **Sofomax**® when used in combination with Ribavirin include:

- Tiredness
- Headache

The most common side effects of **Sofomax**® when used in combination with PEG interferon Alfa and Ribavirin include:

- Tiredness
- Headache
- Nausea
- Difficulty sleeping
- Low RBC count

Precautions

Patients who develop signs or symptoms of bradycardia should seek medical evaluation immediately. Symptoms may include near-fainting or fainting, dizziness or lightheadedness, malaise, weakness, excessive tiredness, shortness of breath, chest pains, and confusion or memory problems.

Contraindications

Sofosbuvir is contraindicated in patients having Amiodarone, Carbamazepine, Phenytoin, Phenobarbital, Oxcarbazepine, Rifabutin, Rifampin, Rifapentine, Tipranavir and Ritonavir.

Drug interactions

Sofosbuvir has drug-drug interactions with Cyclosporine, Darunavir, Efavirenz, Emtricitabine, Tenofovir Disoproxil Fumarate, Methadone, Rilpivirine, and Tacrolimus.

Pharmaceutical precautions

Sofomax® 400 mg tablet: Store in a cool (below 30° C) and dry place. Protect from light. Keep away from the reach of children

Presentation

Sofomax® 400 mg tablet: Each coated tablet contains Sofosbuvir INN 400 mg.

Package quantities

Sofomax® 400 mg tablet: Carton of 7 tablets in blister pack.

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