Suvirux™

Sofosbuvir 400 mg

COMPOSITION
Suvirux™ Tablet: Each film coated tablet contains Sofosbuvir INN 400 mg.

PHARMACOLOGY
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. It is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active uridine analog triphosphate (GS-461203), which can be incorporated into HCV RNA by the NS5B polymerase and acts as a chain terminator.

INDICATION
Suvirux™ 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 Sofosbuvir is one 400 mg tablet, taken orally, once daily with or without food.
It should be administered in combination with Ribavirin or in combination with Pegylated Interferon and Ribavirin for the treatment of HCV. The recommended treatment regimen and duration for Sofosbuvir combination therapy is provided in below table:

Patient Population	Treatment Regimen	Duration
Genotype 1 or 4	Sofosbuvir + Peginterferon alfa + Ribavirin	12 weeks
Genotype 2	Sofosbuvir + Ribavirin	12 weeks
Genotype 3	Sofosbuvir + Ribavirin	24 weeks

*Dosage of Ribavirin is weight-based (<75 kg = 1000 mg and ≥75 kg = 1200 mg).
The daily dosage of Ribavirin is administered orally in two divided doses with food.

A dosage recommendation cannot be made for patients with severe renal impairment or end stage renal disease.

SIDE EFFECTS
The most common adverse events (at least 20%) for combination with Ribavirin or in combination with Pegylated Interferon 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
Serious symptomatic bradycardia may occur in patients taking Amiodarone and Sofosbuvir in combination with another direct acting antiviral, particularly in patients also receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease.

USE IN PREGNANCY AND LACTATION
Pregnancy Category B. There are no adequate and well-controlled studies with Sofosbuvir in pregnant women. Sofosbuvir should be used during pregnancy only if the potential for benefit justifies the potential risk to the fetus.
It is not known whether Sofosbuvir and its metabolites are present in human breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Sofosbuvir and any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

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.

STORAGE
Protect from light. Store in dry place below 30°C. Keep the medicine out of the reach of children.

HOW SUPPLIED
Suvirux™ Tablet: Each box contains 12 Tablets in blister pack.

Manufactured by

SQUARE
FORMULATIONS LTD.
Tangail, Bangladesh

TM- Trade Mark

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