Lesovir-C®

Ledipasvir and Sofosbuvir
Tablet

Description

Lesovir-C® is a fixed-dose combination tablet containing ledipasvir and sofosbuvir for oral administration. Ledipasvir is an HCV NS5A inhibitor and sofosbuvir is a nucleotide analog inhibitor of HCV NS5B polymerase. Following oral administration of Lesovir-C®, ledipasvir median peak concentrations were observed 4 to 4.5 hours post-dose.

Indications

Lesovir-C® is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.

Dosage and Administration

The recommended dosage of Lesovir-C® is one tablet taken orally once daily with or without food.

Recommended Regimens and Treatment Duration for Lesovir-C®

	Duration
Treatment naive with or without cirrhosis	12 weeks
Treatment experienced without cirrhosis	12 weeks
Treatment experienced with cirrhosis	24 weeks

Contraindication

None

Adverse Reactions

The most common adverse reactions (incidence greater than or equal to 10%, all grades) observed with treatment with Lesovir-C® for 8, 12, or 24 weeks are fatigue, headache, nausea, diarrhea and insomnia.

Warnings and Precautions

Bradycardia with amiodarone coadministration: Serious symptomatic bradycardia may occur in patients taking amiodarone, particularly in patients also receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. Coadministration of amiodarone with Lesovir-C® is not recommended. In patients without alternative, viable treatment options, cardiac monitoring is recommended.Use with other drugs containing sofosbuvir, is not recommended.

High Risk Group

Pregnancy Category B:

There are no adequate and well-controlled studies with Lesovir-C® in pregnant women. Because animal reproduction studies are not always predictive of human response, Lesovir-C® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:

It is not known whether Lesovir-C® and its metabolites are present in human breast milk.

Pediatric Use: Safety and effectiveness of Lesovir-C® have not been established in pediatric patients.

Geriatric Use: No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients. No dosage adjustment of Lesovir-C® is warranted in geriatric patients.

Drug Interaction

- Coadministration with amiodarone may result in serious symptomatic bradycardia. Use of Lesovir-C® with amiodarone is not recommended.
- P-gp inducers (e.g., rifampin, St. John's wort): May alter concentrations of ledipasvir and sofosbuvir. Use of Lesovir-C® with P-gp inducers is not recommended.
- Consult the full prescribing information prior to use for potential drug interactions.

Overdosage

No specific antidote is available for overdose with Lesovir-C.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Lesovir-C® tablet: Each bottle contains 7 tablets. Each film coated tablet contains Ledipasvir INN 90 mg & Sofosbuvir INN 400 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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