Dakovir-C®

Daclatasvir

Tablet

Description

Daclatasvir is an inhibitor of NS5A, a nonstructural protein encoded by HCV. Daclatasvir binds to the N-terminus of NS5A and inhibits both viral RNA replication and virion assembly. Characterization of Daclatasvir-resistant viruses, biochemical studies, and computer modeling data indicate that Daclatasvir interacts with the N-terminus within Domain 1 of the protein, which may cause structural distortions that interfere with NS5A functions.

Indications

Daclatasvir works by stopping the hepatitis C virus from multiplying and infecting new cells. This lowers the amount of hepatitis C virus in human body and removes the virus from human blood over a period of time.

Dosage and Administrations

The recommended dosage of Daclatasvir is 60 mg daily taken orally with or without food.

For specific dosage recommendations for Sofosbuvir and Ribavirin refer to the prescribing information.

Table 1: Recommended treatment regimen and duration for Daclatasvir in patients with genotype 1 or 3 HCV

	Patient Population	Treatment and Duration
Genotype 1	Without cirrhosis	Daclatasvir + Sofosbuvir for 12 weeks
	Compensated (Child-Pugh A) cirrhosis	
	Decompensated (Child-Pugh B or C) cirrhosis	Daclatasvir + Sofosbuvir + Ribavirin for 12 weeks
	Post-transplant	
Genotype 3	Without cirrhosis	Daclatasvir + Sofosbuvir for 12 weeks
	Compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis	Daclatasvir + Sofosbuvir + Ribavirin for 12 weeks
	Post-transplant	

Dosage Modifications

Renal or hepatic impairment (any degree): No dose adjustment required

Dosage reduction of Daclatasvir for adverse reactions is not recommended

CYP inhibitors or inducers

- Coadministration with strong CYP3A inhibitors: Decrease dose to 30 mg/day
- Coadministration with moderate CYP3A inducers: Increase dose to 90 mg/day
- Coadministration with strong CYP3A inducers: Contraindicated

Contraindications

When Daclatasvir is used in combination with other agents, the contraindications applicable to those agents are applicable to the combination regimen (see ribavirin and sofosbuvir prescribing information).

Coadministration with drugs that strongly induce CYP3A and, thus, may lead to lower exposure and loss of Daclatasvir efficacy.

Contraindicated drugs

- Anticonvulsants: Carbamazepine, eslicarbazepine, fosphenytoin, phenytoin, oxcarbazepine, pentobarbital, phenobarbital, primidone
- Antimycobacterial agents: Rifabutin, rifampin

Adverse Reactions

Cardiac disorders: Serious symptomatic bradycardia has been reported in patients taking amiodarone who initiate treatment with sofosbuvir in combination with another HCV direct-acting antiviral, including Daclatasvir.

Side Effects

Headache, Fatigue, Difficulty sleeping, Dizziness, Migraine, Nausea, Diarrhoea, Joint pain, Hot flush and Dry mouth.

Warnings and Precautions

Serious symptomatic bradycardia

- Serious symptomatic bradycardia may occur in coadministration with sofosbuvir and amiodarone in combination with another direct acting antiviral (DAA), including Daclatasvir
- Patients also receiving beta-blockers or those with underlying cardiac comorbidities and/or advanced liver disease may be at higher risk

Pregnancy Category

No data found in pregnant women.

If Daclatasvir and Sofosbuvir are administered with Ribavirin, the warnings and precautions for ribavirin, in particular the pregnancy avoidance warning, apply to this combination regimen (see ribavirin prescribing information).

Nursing Mothers: Unknown if distributed in human breast milk. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for the drug and any potential adverse effects on the breastfeed infant from the drug or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of Daclatasvir in children less than 18 years of age have not been established.

Geriatric Use: No dose adjustment of Daclatasvir is warranted in geriatric patients.

Overdose

There is no known antidote for overdose of Daclatasvir. Treatment of overdose with Daclatasvir should consist of general supportive measures, including monitoring of vital signs and observation of the patient's clinical status. Because Daclatasvir is highly protein bound (>99%), dialysis is unlikely to significantly reduce plasma concentrations of the drug.

Pharmaceutical Precautions

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

Commercial Pack

Dakovir-C® 30 Tablet: Each bottle contains 14 tablets. Each film coated tablet contains Daclatasvir Dihydrochloride INN 32.97 mg equivalent to Daclatasvir 30 mg.

Dakovir-C® 60 Tablet: Each bottle contains 14 tablets. Each film coated tablet contains Daclatasvir Dihydrochloride INN 65.94 mg equivalent to Daclatasvir 60 mg.

BEXIMCO PHARMA

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