DACLIT 30mg 60mg

ڈیکلیٹ

(Daclatasvir)

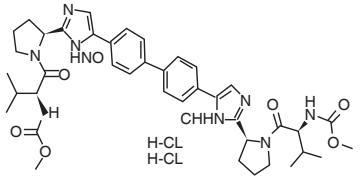
Tablets

DESCRIPTION:

DACLIT (daclatasvir) is an inhibitor of HCV nonstructural protein 5A (NS5A). It is carbamic acid,N,N-[[1,1¬biphenyl]-4,4-diylbis[1H-imidazole-5,2-diyl-(2S)-2,1-pyrrolidinediyl[(1S)-1-(1-methylethyl)-2¬oxo-2,1-ethanediyl]]]bis-, C,C-dimethyl ester, hydrochloride (1:2). Its molecular formula is $C_{40}H_{52}Cl_2N_8O_6$, and its molecular weight is 811.806g/mol.

MECHANISM OF ACTION:

Daclatasvir is a direct-acting antiviral agent (DAA) against the hepatitis C virus. It is an inhibitor of nonstructural protein 5A (NS5A), a multifunctional protein that is an essential component of the HCV replication complex. Daclatasvir inhibits both viral RNA replication and virion assembly.



COMPOSITION:

DACLIT 30mg Tablets

Each film-coated tablet contains:
Daclatasvir Dihydrochloride eq. to
Daclatasvir.....30mg
Innovator's Specs.

DACLIT 60mg Tablets

Each film-coated tablet contains:
Daclatasvir Dihydrochloride eq. to
Daclatasvir.....60mg
Innovator's Specs.

INDICATIONS AND USAGE:

DACLIT is indicated for use with sofosbuvir, with or without ribavirin, for the treatment of patients with chronic hepatitis C virus (HCV) genotype 1 or genotype 3 infection.

Limitations of Use: Sustained virologic response (SVR12) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving DACLIT in combination with sofosbuvir for 12 weeks.

PHARMACOKINETICS:

In patients following multiple oral doses of daclatasvir tablet, from 1mg to 100mg once daily, peak plasma concentrations occurred within 2 hours post dose. The absolute bioavailability is 67%.In healthy subjects, administration of a daclatasvir 60mg tablet after a high-fat, high-caloric meal decreased daclatasvir Cmax and AUC(0-inf) by 28% and 23%, respectively. With multiple dosing, protein binding of daclatasvir in HCV-infected subjects was approximately 99% and independent of dose at the dose range studied (1-100 mg).Following single-dose oral administration of 25 mg 14C-daclatasvir in healthy subjects, the majority of radioactivity in plasma was predominately attributed to parent drug (97% or greater).

Following single-dose oral administration of 25 mg 14C-daclatasvir in healthy subjects, 88% of total radioactivity was recovered in feces and 6.6% of the dose was excreted in the urine. Following multiple dose administration of daclatasvir in HCV-infected subjects, the terminal elimination half-life of daclatasvir ranged from approximately 12 to 15 hours.

DOSAGE & ADMINISTRATION:

60 mg taken orally once daily with or without food in combination with sofosbuvir with or without ribavirin.

USE IN SPECIFIC POPULATIONS:

Pregnancy: In animal reproduction studies in rats and rabbits, no evidence of fetal harm was observed with oral administration of daclatasvir. However, embryofetal toxicity was observed in rats and rabbits at maternally toxic doses that produced exposures of 33 and 98 times the human exposure, respectively, at the RHD of 60 mg of daclatasvir.

Nursing Mothers: Daclatasvir was present in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for daclatasvir and any potential adverse effects on the breastfed child from daclatasvir or from the underlying maternal condition. If daclatasvir is administered with ribavirin, the nursing mother's information for ribavirin also applies to this combination regimen.

Pediatric Use: Safety and effectiveness of daclatasvir in pediatric patients younger than 18 years of age have not been established.

Renal Impairment: No dosage adjustment of daclatasvir is required for patients with any degree of renal impairment.

CONTRAINDICATIONS:

• When daclatasvir is used in combination with other agents, the contraindications applicable to those agents are applicable to the combination regimen. Refer to the respective prescribing information for a list of contraindications.

Daclatasvir is contraindicated in combination with drugs that strongly induce CYP3A Contraindicated drugs include, Anticonvulsants including phenytoin, carbamazepine, Antimycobacterial agents like rifampin.

WARNINGS AND PRECAUTIONS:

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions: The concomitant use of daclatasvir and other drugs may result in known or potentially significant drug interactions, some of which may lead to,

• loss of therapeutic effect of daclatasvir and possible development of resistance,

• dosage adjustments of concomitant medications or daclatasvir,

• possible clinically significant adverse reactions from greater exposures of concomitant drugs or daclatasvir.

Serious Symptomatic Bradycardia When Coadministered with Sofosbuvir and Amiodarone. Postmarketing cases of symptomatic bradycardia and cases requiring pacemaker intervention have been reported.

Risks Associated with Ribavirin Combination Treatment: 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.

The U.S. FDA has warned about the reactivation of Hep-B infection in patients treated with direct acting anti-virals resulted in serious liver problems or death.

SIDE EFFECTS:

Slow heart rate (bradycardia): daclatasvir combination treatment with sofosbuvir may result in slowing of the heart rate (pulse) along with other symptoms when taken with amiodarone, a medicine used to treat certain heart problems. The most common side effects of daclatasvir when used in combination with sofosbuvir include headache, and tiredness. The most common side effects of daclatasvir when used in combination with sofosbuvir and ribavirin include headache, anemia, tiredness, and nausea.

DRUG INTERACTIONS:

The potential drug interactions between DACLIT tablets and moderate or strong inducers of CYP3A, substrates of P-glycoprotein transporter (P-gp), organic anion transporting polypeptides (OATP) 1B1 and 1B3, and breast cancer resistance protein (BCRP), HIV antiviral agents, protease inhibitors, antiretrovirals, Non-nucleoside reverse transcriptase inhibitors (NNRTI), Strong CYP3A inhibitors, Anticoagulants, Cardiovascular agents, Lipid-lowering agents, and Narcotic Analgesic/Treatment of Opioid Dependence have been evaluated.

OVERDOSE

There is no known antidote for overdose of daclatasvir. Daclatasvir is highly protein bound (>99%), dialysis is unlikely to significantly reduce plasma concentrations of the drug.

INSTRUCTIONS:

Dosage as directed by the physician.
Store below 30°C.
Protect from heat, light & moisture.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

DACLIT 30mg Tablets:

DACLIT (Daclatasvir) 30mg tablets are available in Alu-Alu blister pack of 2x14's with a pakage insert.

DACLIT 60mg Tablets:

DACLIT (Daclatasvir) 60mg tablets are available in Alu-Alu blister pack of 2x14's with a pakage insert.

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی، گرمی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کریں۔

For detailed information please contact:

GENIX

GENIX PHARMA PRIVATE LIMITED

44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.
UAN: +92-21-111-10-10-11, Fax: +92-21-111-10-10-22
E-mail: info@genixpharma.com Web.: www.genixpharma.com