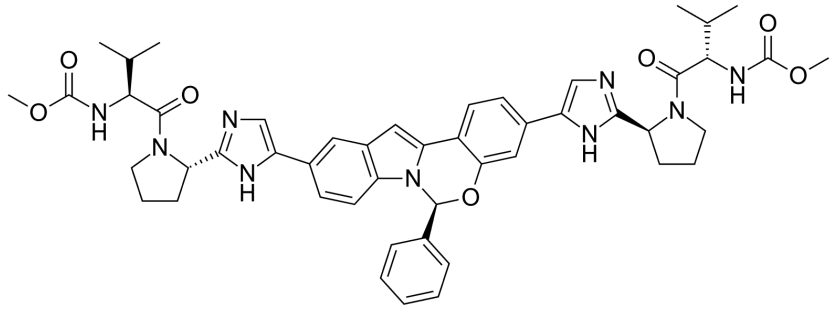
Brand Name: Zepatier
Generic: elbasvir, grazoprevir
Type: small molecule
Year Accepted/Phase: 2016

Mechanism:

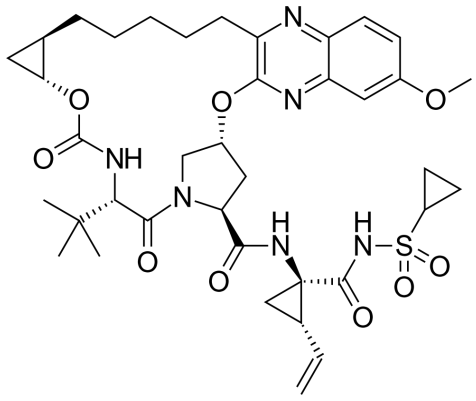
Elbasvir: Inhibits the NS5A protein, which is essential for viral replication and assembly.
Grazoprevir: Inhibits the NS3/4A protease, which is necessary for viral polyprotein processing and replication.

Chemical Structure:

elbasvir



grazoprevir



Indication:

Zepatier is indicated for the treatment of chronic HCV genotype 1 or 4 infection in adults, with or without ribavirin.

Clinical trials:

C-EDGE TN Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/30233138/

Purpose: Evaluate the efficacy and safety of Zepatier in treatment-naive HCV genotype 1, 4, or 6-infected patients.
Dates: Conducted from 2013 to 2015.
Results: The C-EDGE TN trial demonstrated that 95% of patients achieved sustained virologic response at 12 weeks post-treatment (SVR12). The regimen was well-tolerated with a favorable safety profile.
Impact: The trial provided strong evidence for the effectiveness of Zepatier in a broad population of treatment-naive patients with HCV genotype 1, 4, or 6, supporting its use as a first-line therapy.

C-EDGE CO-STAR Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/27537841/

Purpose: Assess the efficacy and safety of Zepatier in HCV-infected patients receiving opioid agonist therapy.
Dates: Conducted from 2013 to 2015.
Results: The C-EDGE CO-STAR trial found that 91% of patients achieved SVR12. The study demonstrated that Zepatier is effective and well-tolerated in a challenging population of patients with HCV undergoing treatment for opioid dependence.
Impact: These results underscored the utility of Zepatier in a real-world setting, including populations with co-morbidities such as substance use disorders.

C-SURFER Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/26456905/

Purpose: Evaluate the efficacy and safety of Zepatier in HCV genotype 1-infected patients with chronic kidney disease (CKD) stage 4 or 5.
Dates: Conducted from 2013 to 2015.
Results: The C-SURFER trial showed that 94% of patients achieved SVR12. The study highlighted the effectiveness of Zepatier in patients with severe renal impairment, a group often excluded from HCV clinical trials.
Impact: The findings supported the use of Zepatier in HCV-infected patients with advanced CKD, providing a treatment option for this high-risk population.

C-EDGE TE Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/28256747/

Purpose: Assess the efficacy and safety of Zepatier in treatment-experienced HCV genotype 1, 4, or 6-infected patients.
Dates: Conducted from 2013 to 2015.

Results: The C-EDGE TE trial demonstrated that 94% of patients achieved SVR12 with a 12-week regimen, and 97% with a 16-week regimen. The study included patients who had failed prior treatment with pegylated interferon and ribavirin.
Impact: This trial confirmed the effectiveness of Zepatier in patients who had not responded to previous therapies, expanding its use to a broader range of HCV-infected patients.