Daklinza

Generic Name: daclatasvir

Pronunciation: da-KLIN-za

Drug Class: NS5A Inhibitors

Company: Bristol-Myers Squibb

Approval Status: Approved

Generic Version Available: No

Experimental Code: BMS 790052

Drug Indication

Daklinza is approved for use with Sovaldi (sofosbuvir) for the treatment of chronic hepatitis C genotypes 1 and 3. Testing prior to initiation: HCV genotype 1a with cirrhosis, consider testing for the presence of virus with NS5A resistance-associated polymorphisms.

General Info

- Daklinza was approved by the U.S. Food and Drug Administration for use by people living with hepatitis C on July 24, 2015.
- In clinical trials, 97 percent of genotype 1 participants who were coninfected with HCV/HIV were cured with 12 weeks of therapy. Approximately 90 percent of treatment-naive genotype 3 participants were cured with 12 weeks of therapy; treatment-experienced participants had 86 percent cure rates with 12 weeks of treatment. Genotype 3 participants without cirrhosis, regardless of treatment history, had 96 percent cure rates; participants with cirrhosis had 63 percent cure rates.

Dosage

Adult Dose: One tablet taken orally once daily in combination with Sovaldi. May be taken with or without food. The optimal duration of Daklinza plus Sovaldi for people with cirrhosis has not been established.

Pediatric Dose: N/A

Dosing Info: Treatment is 12 weeks. For specific treatment recommendations, see Hepatitis C Treatment-Naive Recommendations or Hepatitis C Re-treatment Recommendations.

Side Effects

Side effects associated with Daklinza are considered mild. The most common are headache, fatigue, nausea, and diarrhea.

Drug Interactions

- For a review of drug interactions, including prescription and over-the-counter medications and supplements that should not be taken with Daklinza or may require dose adjustments, consult the Daklinza package insert.

Other Info

- Warning: Patients who are coinfected with hepatitis B and C who take this medication may be at risk of hepatitis B virus (HBV) reactivation. Before taking this medication, be sure your doctor has tested you for evidence of current or prior hepatitis B virus infection. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in serious hepatitis flares, liver failure, and death.
- There are no adequate, well-controlled studies in pregnant women who have taken Daklinza. Daklinza should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- The safety of breast feeding while taking Daklinza has not been established.

For More Info: https://www.hepmag.com/tag/daklinza

Co-Pay Program Info:
http://www.hepmag.com/basics/hepatitis-c-basics/paying-hepatitis-c-treatment

Patient Assistance Program Info:
http://www.hepmag.com/basics/hepatitis-c-basics/paying-hepatitis-c-treatment

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