

Daklinza[™] (daclatasvir) – Product discontinuation

- On January 4, 2019, the <u>FDA announced</u> the discontinuation of Bristol Myers Squibb's <u>Daklinza</u> (<u>daclatasvir</u>) 30 mg and 60 mg tablets.
 - Previously, the FDA announced the discontinuation of Daklinza 90 mg tablets with planned distribution ceasing in December 2018.
 - Bristol Myers Squibb has planned to cease distribution for Daklinza 30 mg and 60 mg tablets in June 2019.
 - All Daklinza tablets are now discontinued.
- Daklinza is indicated for use with <u>Sovaldi[®] (sofosbuvir)</u>, with or without <u>ribavirin</u>, for the treatment of patients with chronic hepatitis C virus (HCV) genotype 1 or genotype 3 infection.
 - The sustained virologic response (SVR12) rates are reduced in genotype 3 patients with cirrhosis receiving Daklinza in combination with sofosbuvir for 12 weeks.
- Daklinza carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.



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