



Vosevi[®] (sofosbuvir/velpatasvir/voxilaprevir) Crushing or Splitting Tablets

This document is in response to your request for information regarding the crushing or splitting of Vosevi[®] (sofosbuvir/velpatasvir/voxilaprevir [SOF/VEL/VOX]) tablets.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.

Product Labeling¹

There is no information in the SOF/VEL/VOX product labeling about the crushing or splitting of SOF/VEL/VOX.

Available Data on Crushing or Splitting SOF/VEL/VOX Tablets

Gilead Data

There are no Gilead studies evaluating the efficacy, safety, and pharmacokinetic parameters of a disintegrated, crushed, or split SOF/VEL/VOX tablet versus the whole tablet in a randomized controlled trial.

SOF/VEL/VOX tablets are not enteric-coated and do not possess a sustained-release mechanism. According to the European Summary of Product Characteristics, it is recommended that film-coated tablets are not chewed or crushed due to their bitter taste.²

Non-Gilead Data

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and January 14, 2025, using the search terms Vosevi, velpatasvir, sofosbuvir, voxilaprevir, cutting, crushing, splitting tablets, and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc, VOSEVI[®] (sofosbuvir/velpatasvir/voxilaprevir [SOF/VEL/VOX]) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Vosevi, Gilead Sciences Ireland UC. Vosevi 400 mg/100 mg/100 mg film-coated tablets. Summary of Product Characteristics (SmPC). Carrigtohill, County Cork, Ireland. Revised May. 2020.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Vosevi US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 <https://www.gilead.com/utility/contact/report-an-adverse-event>

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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