



# Vosevi<sup>®</sup> (sofosbuvir/velpatasvir/voxilaprevir) Crushing or Splitting Tablets

This document is in response to your request for information regarding the crushing or splitting of Vosevi<sup>®</sup> (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](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vosevi/vosevi_pi).**

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## Product Labeling<sup>1</sup>

There is no information in the SOF/VEL/VOX product label about the crushing or splitting of SOF/VEL/VOX; therefore, it is not recommended that SOF/VEL/VOX be administered as a crushed or split tablet. The decision to administer SOF/VEL/VOX as a crushed or split tablet is at the discretion of the prescribing or dispensing health care professional.

For the individual components of SOF/VEL/VOX, SOF has a solubility of  $\geq 2$  mg/mL across the pH range of 2 to 7.7 at 37°C and is slightly soluble in water; VEL is practically insoluble ( $< 0.1$  mg/mL) above pH 5, slightly soluble (3.6 mg/mL) at pH 2, and soluble ( $> 36$  mg/mL) at pH 1.2; and VOX is practically insoluble ( $< 0.1$  mg/mL) below pH 6.8.

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## 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 compared with 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.<sup>2</sup>

### Non-Gilead Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to January 8, 2026, 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.

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## 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](http://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](http://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](http://www.accessdata.fda.gov/scripts/medwatch)

## Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

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