

# Sovaldi<sup>®</sup> (sofosbuvir) Crushing or Splitting Tablets

This document is in response to your request for information regarding the crushing or splitting of Solvaldi<sup>®</sup> (sofosbuvir [SOF]) 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/sovaldi/sovaldi\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi).**

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

There is no information in the SOF US product label about the crushing or splitting of SOF tablets; therefore, it is not recommended that SOF be administered as a crushed or split tablet. 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.

Please refer to the US product label for complete product information on SOF oral pellets.

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## Available Data on Crushing or Splitting SOF Tablets

### Gilead Data

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

SOF tablets are not enteric-coated and do not possess a sustained-release mechanism. According to the European Summary of Product Characteristics, SOF tablets should not be chewed or crushed due to the bitter taste of the active substance.<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 Sovaldi, sofosbuvir, and cutting, crushing, splitting tablets and related search terms. No relevant citations were found.

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## References

1. Enclosed. Gilead Sciences Inc, SOVALDI<sup>®</sup> (sofosbuvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Sovaldi, Gilead Sciences Ireland UC. Sovaldi 400 mg film-coated tablets. Summary of Product Characteristics (SmPC). County Cork, Ireland.

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## Product Label

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

[www.gilead.com/-/media/files/pdfs/medicines/liver-disease/sovaldi/sovaldi\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/sovaldi/sovaldi_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)

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