

# Sovaldi® (sofosbuvir)

## Crushing or Splitting Tablets

This document is in response to your request for information regarding the crushing or splitting of Sovaldi® (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 labeling about the crushing or splitting of SOF tablets. Please refer to the US product labeling for completed 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 versus 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, BIOSIS Previews, and Embase databases for studies published between 1946 and January 14, 2025, 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® (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. Revised: October. 2017.

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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)

## 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.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement ([www.gilead.com/privacy-statements](http://www.gilead.com/privacy-statements)) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact [privacy@gilead.com](mailto:privacy@gilead.com).

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