



## Vosevi® (SOF/VEL/VOX)

# Storage and Stability

This document is in response to your request for extended storage and stability information of Vosevi® (sofosbuvir/velpatasvir/voxilaprevir [SOF/VEL/VOX]) 400/100/100 mg tablets and does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Vosevi® (SOF/VEL/VOX) should be stored according to the product label.

**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>

Each bottle contains 28 tablets, polyester coil, silica gel desiccant, and is closed with a child-resistant closure. Store below 30°C (86°F). Dispense only in original container.

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## Alternative Storage and Stability Information<sup>2</sup>

The table below summarizes available data from in-house studies regarding the storage of SOF/VEL/VOX tablets in varying conditions. The “acceptable duration” refers to the stability of SOF/VEL/VOX tablets in the specified packaging and storage condition, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

**Table 1. Summary of Extended Stability Data for SOF/VEL/VOX Tablets<sup>2</sup>**

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/60% relative humidity <sup>a</sup>	Petri dish	4 weeks
30°C (86°F)/75% relative humidity	Original bottle, broken seal	60 days
40°C (104°F)/75% relative humidity	Original bottle	6 months
60°C (140°F)	Original bottle	14 days
-20°C (-4°F)	Original bottle	14 days

<sup>a</sup>Tablets are stored outside of the commercial packaging configuration in an open petri dish in a stability chamber.

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## References

1. Enclosed. Gilead Sciences Inc, VOSEVI® (sofosbuvir/velpatasvir/voxilaprevir [SOF/VEL/VOX]) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

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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)

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