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GILEAD | Medical Information

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.

Product Labeling[1]

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.

Alternative Storage and Stability Information[2]

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[2]

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/60% relative humidity[a]	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

[a]Tablets are stored outside of the commercial packaging configuration in an open petri dish in a stability chamber.

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.

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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