GILEAD | Medical Information

# Epclusa® (sofosbuvir/velpatasvir) Oral Pellets Storage and Stability

This document is in response to your request for extended storage and stability information of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) 200 mg/50 mg and 150 mg/37.5 mg oral pellets 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. Epclusa® (SOF/VEL) 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/epclusa/epclusa_pi.**

## Product Labeling[1]

Each carton contains 28 unit-dose packets.

Store below 30°C (86°F). Do not use if carton tamper-evident seal or packet has been opened or damaged.

## Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of SOF/VEL oral pellets in varying conditions. The “acceptable duration” refers to the stability of SOF/VEL oral pellets 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 Oral Pellets[2]**

| Storage Condition | Package Type | Acceptable Duration |
|---|---|---|
| 40°C (104°F)/75% relative humidity | Original packet | 6 months |
| 50°C (122°F) | Original packet | 2 weeks |
| -20°C (-4°F) | Original packet | 1 month |

## References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) 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 Epclusa US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_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 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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