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GILEAD | Medical Information

Harvoni® (ledipasvir/sofosbuvir) Storage and Stability

This document is in response to your request for extended storage and stability information of Harvoni® (ledipasvir/sofosbuvir [LDV/SOF]) 90/400 mg and 45/200 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. Harvoni® (LDV/SOF) 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/harvoni/harvoni_pi.

Product Labeling[1]

Each bottle contains 28 tablets, a silica gel desiccant and polyester coil, and is closed with a child-resistant closure. Store below 30°C (86°F). Dispense only in original container. Do not use if seal over bottle opening is broken or missing.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of LDV/SOF tablets in varying conditions. The “acceptable duration” refers to the stability of LDV/SOF 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 LDV/SOF Tablets[2]

Storage Conditions	Package Type	Acceptable Duration
Open dish 25°C (77°F)/60% relative humidity[a]	Petri dish	45 days
Open dish 30°C (86°F)/75% relative humidity[a]	Petri dish	45 days
40°C (104°F)/75% relative humidity	Original bottle	6 months
25°C (77°F)/60% relative humidity	Original bottle, broken seal	30 days
30°C (86°F)/75% relative humidity	Original bottle, broken seal	30 days
50°C (122°F)	Original bottle	45 days
5°C (41°F)	Original bottle	45 days
60° (140°F)	Original bottle	14 days
-20°C (-4°F)	Original bottle	28 days

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

References

1. HARVONI, Gilead Sciences Inc. HARVONI® (ledipasvir and sofosbuvir) Tablets, for Oral Use. HARVONI® (ledipasvir and sofosbuvir) Oral Pellets. U. S. 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 Harvoni US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/harvoni/harvoni_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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