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GILEAD | Medical Information

Harvoni® (ledipasvir/sofosbuvir) Oral Pellets Storage and Stability

This document is in response to your request for extended storage and stability information of Harvoni® (ledipasvir/sofosbuvir [LDV/SOF]) 45 mg/200 mg and 33.75 mg/150 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. 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 carton contains 28 unit-dose packets. Store below 30°C (86°F).

Do not use if carton tamper-evident seal or packet seal is broken or damaged.

Alternative Storage and Stability Information[2]

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