GILEAD | Medical Information

Letairis® (ambrisentan) Storage and Stability

This document is in response to your request for extended storage and stability information of Letairis® (ambrisentan [ABS]) 5 mg and 10 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. Letairis® (ABS) 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/cardiovascular/letairis/letairis_pi.

Product Labeling[1]

ABS is supplied as a 5- and 10-mg film-coated tablet. Each strength tablet is supplied as a 10- and 30-count blister package or bottle.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59–86°F). Store ABS in its original packaging.

Alternative Storage and Stability Information[2]

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

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/60% relative humidity	Open petri dish[a]	6 weeks
30°C (86°F)/65% relative humidity	Open petri dish[a]	6 weeks
-20°C (-4°F)	Original sealed bottle	4 days
40°C (104°F)/75% relative humidity	Original sealed bottle	6 months
60°C (140°F)	Original sealed bottle	4 days

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

References

1. Enclosed. Gilead Sciences Inc, LETAIRIS® (ambrisentan) 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 Letairis US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/cardiovascular/letairis/letairis_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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