

Givosiran: Temperature Excursions

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The full Prescribing Information for GIVLAARI® (givosiran) is provided [here](#). Alnylam Pharmaceuticals does not recommend the use of its products in any manner that is inconsistent with the approved Prescribing Information. This resource may contain information that is not in the approved Prescribing Information.

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SUMMARY

- As stated in the Prescribing Information, givosiran is to be stored between 2°C to 25°C (36°F to 77°F) in its original container until ready to use.¹
- Stability data results from 6 batches of finished product were within specification for the samples stored under long-term conditions. Based on the available stability data, the proposed shelf-life is 36 months, not to exceed 25°C.²

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GIVLAARI PRESCRIBING INFORMATION – RELEVANT CONTENT

The **HOW SUPPLIED/STORAGE AND HANDLING** provides the following information¹:

Storage and Handling

Store at 2°C to 25°C (36°F to 77°F).

Store GIVLAARI in its original container until ready for use.

ADDITIONAL STABILITY INFORMATION

Stability data from 6 batches of finished product, some at full commercial scale, stored for up to 48 months under long term conditions (2-8°C) and (25°C/60% RH) and for up to 6 months under accelerated conditions (40°C/75% RH) according to the ICH guidelines were provided. Samples were stored in the up-right and inverted position to increase the contact time with the stopper. The registration stability batches of medicinal product were identical to those proposed for marketing and were packed in the primary packaging proposed for marketing.²

Samples were tested for the parameters listed in the release specifications, including appearance, assay, purity and impurity, pH, osmolality, particulate matter, bacterial endotoxins, sterility, extractable volume, and container closure integrity, with the exception of identity. The analytical

procedures used were stability indicating. All results were within specification for the samples stored under long-term conditions. No significant changes have been observed under the named conditions.²

Based on the available stability data, the proposed shelf-life is 36 months, not to exceed 25°C. Keep vial in the outer carton to protect from light.²

ABBREVIATIONS

ICH = International Council for Harmonisation; RH = relative humidity.

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REFERENCES

1. GIVLAARI (givosiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.
2. Givlaari: EPAR – Public assessment report. European Medicines Agency. Published March 09, 2020. Accessed August 21, 2024. https://www.ema.europa.eu/documents/assessment-report/givlaari-epar-public-assessment-report_en.pdf.