Lumasiran: Temperature Cycling and Stability

The following information is provided in response to your unsolicited inquiry. It is intended to provide you with a review of the available scientific literature and to assist you in forming your own conclusions in order to make healthcare decisions. This document is not for further dissemination or publication without authorization.

The full Prescribing Information for OXLUMO® (lumasiran) 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.

If you are seeking additional scientific information related to Alnylam medicines, you may visit the Alnylam US Medical Affairs website at RNAiScience.com.

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Label Information – Additional Stability Information – Abbreviations – References

OXLUMO PRESCRIBING INFORMATION – RELEVANT CONTENT

The **HOW SUPPLIED/STORAGE AND HANDLING** section provides the following information[1]:

How Supplied

OXLUMO is a clear, colorless-to-yellow solution available in single-dose vials of 94.5 mg/0.5 mL in cartons containing one vial (NDC 71336-1002-1).

Storage and Handling

Store at 2°C to 25°C [36°F to 77°F].

Store OXLUMO in its original container until ready for use.

ADDITIONAL STABILITY INFORMATION

The stability of lumasiran drug product was tested in varying conditions.[2]

Stability data was assessed from ten batches of finished product stored for up to 60 months under long term conditions (2°C to 8°C, 25°C/60% RH, 30°C/75% RH) and for up to 6 months under accelerated conditions (40°C/75% RH), according to ICH guidelines.[2,3] The finished product batches were representative of those proposed for marketing and were packed in the primary packaging proposed for marketing.[2]

A small-scale batch of lumasiran drug product was used to study thermal stress, cyclic stress, and photostability. Results obtained during the assessment of thermal and cyclic stress showed the final product was resistant to heat degradation under the parameters studied at up to 14 days at 60°C (140°F) and freeze-thaw cycling from -20°C to 60°C (-4°F to 140°F) with cumulative exposure periods of 12 days under each condition.[2]

The stability batches stored under long term conditions and used to study thermal stress, cyclic stress, and photostability were tested in line with the shelf-life specifications. The currently available stability results at long-term showed no obvious trends and were within specification limits.[2]

ABBREVIATIONS

C = Celsius; F = Fahrenheit; ICH = International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; RH = relative humidity.

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REFERENCES

1. OXLUMO (lumasiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals.
2. Oxlumo : EPAR – Public assessment report. European Medicines Agency. Published November 25, 2020. Accessed April 15, 2026. https://www.ema.europa.eu/documents/assessment-report/oxlumo-epar-public-assessment-report_en.pdf.
3. Alnylam Pharmaceuticals. Data on file. MED-ALL-GO1-2500002.