Lumasiran: Stability in Prepared Syringe

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.

INDEX

OXLUMO PRESCRIBING INFORMATION – RELEVANT CONTENT

The DOSAGE AND ADMINISTRATION section provides the following information[1]:

Administration Instructions

OXLUMO is intended for subcutaneous use and should be administered by a healthcare professional.

Visually inspect the drug product solution. Do not use if it contains particulate matter or if it is cloudy or discolored. OXLUMO is a sterile, preservative-free, clear, colorless-to-yellow solution. It is supplied in a single-dose vial, as a ready-to-use solution that does not require additional reconstitution or dilution prior to administration.

- *Use aseptic technique.*
- *Divide injection volumes greater than 1.5 mL equally into multiple syringes.*
- *For volumes less than 0.3 mL, a sterile 0.3-mL syringe is recommended. If using a 0.3 mL (30 unit) insulin syringe, 1-unit markings indicate 0.01 mL.*
- *Administer subcutaneous injection into the abdomen, thigh, or the side or back of the upper arms. Rotate injection sites. Do not inject into scar tissue or areas that are reddened, inflamed, or swollen.*
    - *If injecting into the abdomen, avoid the area around the navel.*
    - *If more than one injection is needed for a single dose of OXLUMO, the injection sites should be at least 2 cm apart.*
- *Discard unused portion of the drug.*

The HOW SUPPLIED/STORAGE AND HANDLING section provides the following information[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

In-use studies have been conducted using commercial 1 mL and 3 mL polycarbonate or polypropylene syringes and needle bore sizes of 21 G and 30 G to assess the stability of lumasiran, which demonstrated, by purity testing and assay, no significant differences of the syringe samples to the control vials when the

syringe samples were stored at 25°C for 8 hours and at 2°C to 8°C for 48 hours. Furthermore, real time stability data shows that lumasiran is stable when stored at 2°C to 30°C for the duration of its shelf life (36 months).[2]

ABBREVIATIONS

C = Celsius; F = Fahrenheit; G = gauge.

Updated 31 January 2025

REFERENCES

1. OXLUMO (lumasiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals.
2. Oxlumo : EPAR – Public assessment report. European Medicines Agency. Published November 25, 2020. Accessed January 31, 2025. https://www.ema.europa.eu/documents/assessment-report/oxlumo-epar-public-assessment-report_en.pdf.