

Lumasiran: Preparation and Administration

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.

SUMMARY

- OXLUMO is intended for subcutaneous use and should be administered by a healthcare professional. The recommended dosing regimen of OXLUMO consists of loading doses (monthly for 3 doses) followed by maintenance doses (beginning 1 month after the last loading dose).¹
- If a dose is delayed or missed, administer OXLUMO as soon as possible. Resume prescribed monthly or quarterly dosing, from the most recently administered dose.¹

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OXLUMO PRESCRIBING INFORMATION – RELEVANT CONTENT

The DOSAGE AND ADMINISTRATION section provides the following information¹:

Recommended Dosage

The recommended dosing regimen of OXLUMO consists of loading doses (monthly for 3 doses) followed by maintenance doses (beginning 1 month after the last loading dose) administered subcutaneously as shown in Table 1.

Dosing is based on actual body weight.

Table 1. OXLUMO Weight-Based Dosing Regimen

Body Weight	Loading Dose	Maintenance Dose
<i>Less than 10 kg</i>	<i>6 mg/kg once monthly for 3 doses</i>	<i>3 mg/kg once monthly, beginning 1 month after the last loading dose</i>
<i>10 kg to less than 20 kg</i>	<i>6 mg/kg once monthly for 3 doses</i>	<i>6 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose</i>
<i>20 kg and above</i>	<i>3 mg/kg once monthly for 3 doses</i>	<i>3 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose</i>

For Patients on Hemodialysis

Administer OXLUMO after hemodialysis if administered on dialysis days.

Missed Dose

If a dose is delayed or missed, administer OXLUMO as soon as possible. Resume prescribed monthly or quarterly dosing, from the most recently administered dose.

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 information¹:

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.

ABBREVIATIONS

C = Celsius; cm = centimeter; F = Fahrenheit; kg = kilogram; mg = milligram; mL = milliliter.

Updated 1 October 2024

REFERENCES

1. OXLUMO (lumasiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals.