# Patisiran: Dosing Schedule

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 ONPATTRO® (patisiran) 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


- As part of the APOLLO and APOLLO-B study protocols, patisiran 0.3 mg/kg was administered once every 21 days (± 3 days).[1,2]


## INDEX



## CLINICAL DATA

**APOLLO Study**

APOLLO was a multicenter, international, randomized (2:1), double-blind, placebo-controlled, phase 3 study designed to assess the efficacy and safety of IV patisiran 0.3 mg/kg every 3 weeks (n=148) versus placebo (n=77) in patients with the polyneuropathy of hATTR. The primary endpoint was the change from baseline in the mNIS+7 at 18 months.[3]

Patisiran Dosing Schedule

As part of the study protocol for the APOLLO study, patisiran 0.3 mg/kg was administered once every 21 days (± 3 days).[1]

**APOLLO-B Study**

APOLLO-B was a multicenter, international, randomized (1:1), double-blind, placebo-controlled, phase 3 study designed to evaluate the efficacy and safety of IV patisiran 0.3 mg/kg every 3 weeks (n=181) versus placebo (n=179) in patients with ATTR with cardiomyopathy, including both hATTR and wtATTR. The primary endpoint was the change from baseline in the 6-MWT at 12 months. After the 12-month double-blind treatment period, all patients received patisiran in an open-label extension period.[4]

Patisiran Dosing Schedule

As part of the study protocol for the APOLLO-B study, patisiran 0.3 mg/kg was administered once every 21 days (± 3 days).[2]

Missed Dose Recommendation

If a patient did not receive a dose of patisiran within the dosing window (±3 days), the delayed dose may be taken up to 7 days after the scheduled visit (ie, +4 days after the +3-day dosing window per the schedule of assessments). If a dose was administered with a delay, the next dose would resume following the original schedule.[2]

## ONPATTRO PRESCRIBING INFORMATION – RELEVANT CONTENT

The DOSAGE AND ADMINISTRATION section provides the following information[5]:

*Dosing Information*

*ONPATTRO should be administered by a healthcare professional.*

*ONPATTRO is administered via intravenous (IV) infusion. Dosing is based on actual body weight.*

*For patients weighing less than 100 kg, the recommended dosage is 0.3 mg/kg once every 3 weeks.*

*For patients weighing 100 kg or more, the recommended dosage is 30 mg once every 3 weeks.*

*Missed Dose*

*If a dose is missed, administer ONPATTRO as soon as possible.*

- *If ONPATTRO is administered within 3 days of the missed dose, continue dosing according to the patient's original schedule.*
- *If ONPATTRO is administered more than 3 days after the missed dose, continue dosing every 3 weeks thereafter.*

## ABBREVIATIONS

6-MWT = 6-minute walk test; ATTR = transthyretin amyloidosis; hATTR = hereditary transthyretin amyloidosis; IV = intravenous; mNIS+7 = modified Neuropathy Impairment Score +7; wtATTR = wild-type transthyretin amyloidosis.

*Updated 19 July 2024*

## REFERENCES


1. Protocol for: Adams D, González-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. *N Engl J Med*. 2018;379(1):11-21. doi:10.1056/NEJMoa1716153
2. Protocol for: Maurer MS, Kale P, Fontana M, et al. Patisiran treatment in patients with transthyretin cardiac amyloidosis. *N Engl J Med*. 2023;389(17):1553-1565. doi:10.1056/NEJMoa2300757
3. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. *N Engl J Med*. 2018;379(1):11-21. doi:10.1056/NEJMoa1716153
4. Maurer MS, Kale P, Fontana M, et al. Patisiran treatment in patients with transthyretin cardiac amyloidosis. *N Engl J Med*. 2023;389(17):1553-1565. doi:10.1056/NEJMoa2300757
5. ONPATTRO (patisiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.