Patisiran: Product 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 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.

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SUMMARY

- Patisiran is stored refrigerated at 2°C to 8°C (36°F to 46°F). If refrigeration is not available, patisiran can be stored at room temperature up to 25°C (up to 77°F) for up to 14 days.[1]
- Patisiran must be filtered and diluted prior to IV infusion. The diluted solution should be administered immediately after preparation. If not used immediately, chemical and physical in-use stability have demonstrated the infusion bag may be stored at room temperature (up to 30°C [86°F]) for up to 16 hours (including infusion time).[1,2]

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ADDITIONAL STABILITY INFORMATION

Product Stability

Chemical and Physical Stability

The stability of the patisiran finished product was assessed on batches stored for up to 36 months under long-term conditions (2-8°C) and for up to 6 months under accelerated conditions (25°C/ 60% RH) following ICH guidelines.[2]

Samples of the patisiran finished product were tested for appearance, purity of active substance, assay, lipid content, siRNA encapsulation, pH, osmolality, particle size, particulate matter, bacterial endotoxins, sterility, and container integrity. All tested parameters were within the specification limits through 36 months.[2]

An in-use study of the chemical and physical stability of the patisiran admixture was conducted. The admixtures were assessed at clinically relevant concentrations representing two-fold differences in patient weight (50 kg and 104 kg) under simulated conditions of use at 30°C±2°C/75%±5% RH, and ambient fluorescent lighting, following simulated infusion using clinically relevant equipment, filters, administration sets, and supplies. The results of the in-use stability assessment confirm the physical and chemical stability of the admixture at clinically relevant concentrations following a 16-hour

hold-time in the infusion bag (0.9% NaCl) at a customary room temperature (up to ICH* climatic Zone IVb) and followed by a simulated infusion under ambient lighting.[2]

Photostability

Photostability testing was performed following the ICH guideline at Q1B with exposure to both cool white fluorescent and near UV light. The results indicated that no special protection from light is required during storage of the patisiran finished product.[2]

Diluted Patisiran Solution Stability

Studies designed to evaluate the stability of the diluted patisiran solution following transport have not been conducted to date.

Patisiran may form small amounts of aggregated particles if stored at room temperature and if subjected to mechanical stress, such as in conditions of shipping, shaking, or vibrations. The dilution of patisiran in saline solution in the infusion bag exposes the patisiran LNP to a diluted, hydrophilic environment that increases the tendency of the LNPs to aggregate. During the time of exposure of patisiran to room temperature, excessive shaking or vibrations may create aggregated particles that can clog the 1.2 µm in-line infusion filter, which may require replacement. Therefore, the infusion of patisiran is recommended to be started as soon as possible after preparation of the admixture with as little disturbance to the infusion bag as possible.[3]

ONPATTRO PRESCRIBING INFORMATION – RELEVANT CONTENT

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

Preparation Instructions

ONPATTRO must be filtered and diluted prior to intravenous infusion. The diluted solution for infusion should be prepared by a healthcare professional using aseptic technique as follows:

- *Remove ONPATTRO from the refrigerator and allow to warm to room temperature. Do not shake or vortex.*
- *Inspect visually for particulate matter and discoloration. Do not use if discoloration or foreign particles are present. ONPATTRO is a white to off-white, opalescent, homogeneous solution. A white to off-white coating may be observed on the inner surface of the vial, typically at the liquid-headspace interface. Product quality is not impacted by presence of the white to off-white coating.*
- *Calculate the required dose of ONPATTRO based on the recommended weight-based dosage.*
- *Withdraw the entire contents of one or more vials into a single sterile syringe.*
- *Filter ONPATTRO through a sterile 0.45 micron polyethersulfone (PES) syringe filter into a sterile container.*
- *Withdraw the required volume of filtered ONPATTRO from the sterile container using a sterile syringe.*
- *Dilute the required volume of filtered ONPATTRO into an infusion bag containing 0.9% Sodium Chloride Injection, USP for a total volume of 200 mL. Use infusion bags that are di(2-ethylhexyl)phthalate-free (DEHP-free).*

- *Gently invert the bag to mix the solution. Do not shake. Do not mix or dilute with other drugs.*
- *Discard any unused portion of ONPATTRO.*
- *ONPATTRO does not contain preservatives. The diluted solution should be administered immediately after preparation. If not used immediately, store in the infusion bag at room temperature (up to 30°C [86°F]) for up to 16 hours (including infusion time). Do not freeze.*

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

Storage and Handling

Store at 2°C to 8°C (36°F to 46°F). Do not freeze. Discard vial if it has been frozen.

If refrigeration is not available, ONPATTRO can be stored at room temperature up to 25°C (up to 77°F) for up to 14 days.

For storage conditions of ONPATTRO after dilution in the infusion bag, see Dosage and Administration section.

ABBREVIATIONS

ICH = International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use; IV = intravenous; LNP = lipid nanoparticle; OLE = open-label extension; RH = relative humidity; siRNA = small interfering ribonucleic acid; UV = ultraviolet.

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REFERENCES

1. ONPATTRO (patisiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.
2. Onpattro : EPAR – Public assessment report. European Medicines Agency. Published October 30, 2018. Accessed June 18, 2026. https://www.ema.europa.eu/documents/assessment-report/onpattro-epar-public-assessment-report_en.pdf.
3. Alnylam Pharmaceuticals. Data on file. MED-ALL-TTR02-2200063.