

Vutrisiran: Storage 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 AMVUTTRA[®] (vutrisiran) 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

- There are no data available to support a preference for storage of vutrisiran at room temperature versus refrigeration. As stated in the Prescribing Information, vutrisiran is to be stored between 2°C to 30°C (36°F to 86°F) in the original carton, until ready for use.¹
- The product expiration date is provided for each syringe and should be utilized to determine if the product is expired. The shelf life of vutrisiran when stored at 2°C to 30°C (36°F to 86°F) is 36 months.²

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AMVUTTRA PRESCRIBING INFORMATION – RELEVANT CONTENT

The HOW SUPPLIED/STORAGE AND HANDLING section provides the following information¹:

How Supplied

AMVUTTRA is a sterile, preservative-free, clear, colorless-to-yellow solution for subcutaneous injection. AMVUTTRA is supplied as 25 mg/0.5 mL solution in a single-dose 1-mL prefilled syringe made from Type I glass with stainless steel 29-gauge needle with a needle shield. The prefilled syringe components are not made with natural rubber latex.

AMVUTTRA is available in cartons containing one single-dose prefilled syringe each.

Storage and Handling

Store at 2°C to 30°C (36°F to 86°F) in the original carton, until ready for use. Do not freeze.

RELEVANT INFORMATION

The product expiration date is provided for each syringe and should be utilized to determine if the product is expired. The shelf life of vutrisiran when stored at 2°C to 30°C (36°F to 86°F) is 36 months.²

Product Stability

The stability of vutrisiran finished product was assessed from three commercial scale batches stored for up to 9 months under long term conditions (2-8°C, 25°C/60% RH and 30°C/75% RH) and for 6 months under accelerated conditions (40°C/75% RH) following the ICH guidelines. Samples were stored horizontally, where horizontal position was considered as worst case due to maximal contact of the aqueous finished product with the plunger and tip cap.³

Samples were tested for appearance, purity, assay, pH, osmolality, particulate matter, volume in container, bacterial endotoxins, sterility, container closure integrity, and mechanism syringe performance. There were no significant changes observed in any of the attributes at either long-term or accelerated conditions.³

Photostability testing was conducted on one batch in accordance with the ICH guideline Q1B. The vutrisiran finished product was considered to be photostable.³

Exposure to thermal cycling for four times between -20°C to 40°C for three consecutive days at each condition showed no adverse effects on the quality of the vutrisiran finished product.³

ABBREVIATIONS

ICH = International Council for Harmonisation; RH = relative humidity.

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REFERENCES

1. AMVUTTRA (vutrisiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.
2. Alnylam Pharmaceuticals. Data on file. MED-US-TTRSC02-2200052.
3. AMVUTTRA : EPAR – Public assessment report. European Medicines Agency. Published July 21, 2022. Accessed May 29, 2024. https://www.ema.europa.eu/en/documents/assessment-report/amvuttra-epar-public-assessment-report_en.pdf.