Givosiran: Temperature Excursions

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 GIVLAARI® (givosiran) 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 stated in the Prescribing Information, givosiran is to be stored between 2°C to 25°C (36°F to 77°F) in its original container until ready to use.[1]
- In the case of a minor excursion during the phase 3 ENVISION study, the investigational product could still be used. Excursions were considered minor if [2]:
  - Temperatures were ≥ -20°C and < 2°C for ≥ 1 hour and ≤ 24 hours, or
  - Between > 8 °C and ≤ 40 °C for ≥ 1 hour and ≤ 24 hours.

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GIVLAARI PRESCRIBING INFORMATION – RELEVANT CONTENT

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

Storage and Handling

Store at 2°C to 25°C (36°F to 77°F).

Store GIVLAARI in its original container until ready for use.

ADDITIONAL STABILITY INFORMATION

The ENVISION study was a phase 3, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of givosiran in patients with a documented diagnosis of AHP. Enrolled patients were randomized on a 1:1 basis to receive subcutaneous injections of givosiran 2.5 mg/kg (n=48) or placebo (n=46) once a month for 6 months, followed by an optional 30-month OLE. The primary endpoint was the annualized rate of composite porphyria attacks among patients with AIP at 6 months.[3,4]

During the ENVISION study, minimally acceptable standards pertaining to the receipt, storage, preparation, dispensing, administration, reconciliation, and return of the investigational product were provided to the trial sites.[2]

Minor excursions, including temperatures ≥ -20°C and < 2°C or between > 8 °C and ≤ 40 °C for ≥ 1 hour and ≤ 24 hours, were required to be documented and reported. In the case of a minor excursion, the investigational product could still be used.[2]

ABBREVIATIONS

AHP = acute hepatic porphyria; AIP = acute intermittent porphyria; OLE = open-label extension

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REFERENCES

1. GIVLAARI (givosiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.
2. Alnylam Pharmaceuticals. Data on file.
3. Balwani M, Sardh E, Ventura P, et al. Phase 3 trial of RNAi therapeutic givosiran for acute intermittent porphyria. *N Engl J Med*. 2020;382(24):2289-2301. doi:10.1056/NEJMoa1913147
4. Kuter DJ, Bonkovsky HL, Monroy S, et al. Efficacy and safety of givosiran for acute hepatic porphyria: Final results of the randomized phase III ENVISION trial. *J Hepatol*. 2023;79(5):1150-1158. doi:10.1016/j.jhep.2023.06.013