

Vutrisiran: Pain in Extremity

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SUMMARY

- In the HELIOS-A study, pain in extremity was reported as an AE in 18 patients (14.8%) in the vutrisiran group over the 18-month treatment period. The events were mild or moderate in severity, and none of them led to treatment discontinuation.^{1,2}
- In the HELIOS-B study, there were no new safety concerns identified involving pain in extremity with the use of vutrisiran.³
- A cumulative post-marketing review of Alnylam’s global safety database did not identify any safety concerns involving pain in extremity with the use of vutrisiran.⁴
- No additional information is available regarding pain in extremity events and their management. The management of pain in the extremity is at the clinical discretion of the healthcare professional.

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CLINICAL DATA

HELIOS-A Study

HELIOS-A was a phase 3, global, randomized, open-label study designed to evaluate the efficacy and safety of vutrisiran in patients with hATTR-PN. Patients were randomized (3:1) to receive either vutrisiran 25 mg every 3 months by subcutaneous injection (n=122) or patisiran 0.3 mg/kg every 3 weeks by IV infusion (as a reference group, n=42) for 18 months. This study used the placebo arm of the APOLLO study as an external control arm (n=77) for the primary endpoint and most other efficacy endpoints. The primary endpoint was the change from baseline in mNIS+7 at 9 months.¹

Pain in Extremity

Pain in extremity events during the HELIOS-A study were reported using the following preferred terms: “Pain in Extremity” and “Limb Discomfort”. During the 18-month treatment period, pain in extremity was reported as an AE in 18 patients (14.8%) in the vutrisiran group, 3 patients (7.1%) in the patisiran

group, and 8 patients (10.4%) in the APOLLO-placebo group.¹ The AEs were mild or moderate in severity, and none of them led to treatment discontinuation. Pain in extremity AEs did not increase over time.²

GLOBAL SAFETY DATABASE

A cumulative post-marketing review of Alnylam Pharmaceuticals' global safety database did not identify any safety concerns involving pain in extremity with the use of vutrisiran.⁴

AMVUTTRA PRESCRIBING INFORMATION – RELEVANT CONTENT

For relevant labeling information, please refer to the following section of the [AMVUTTRA Prescribing Information](#)⁵:

- ADVERSE REACTIONS Section 6.1 Clinical Trials Experience

ABBREVIATIONS

AE = adverse event; hATTR-PN = hereditary transthyretin amyloidosis with polyneuropathy; IV = intravenous; mNIS+7 = modified Neuropathy Impairment Score +7.

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REFERENCES

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