

Note: No limitations on the date of material searched. Search completed through January 22, 2025.

AURLUMYN

- ⦿ AURLUMYN. Prescribing Information. Eicos Sciences, Inc.; 2024. Accessed January 22, 2025. https://aurlumyn.com/sites/aurlumyn-library/files/2024-11/PI_Aurlumyn_iloprost_label_May2024.pdf
- ⦿ FDA approves first medication to treat severe frostbite. News release. US Food and Drug Administration; February 14, 2024. Accessed February 4, 2025. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-medication-treat-severe-frostbite>
- ⦿ Harris E. FDA approves iloprost as first drug to treat severe frostbite. *JAMA*. 2024;331(11):907. doi: 10.1001/jama.2024.1116

Iloprost Study Manuscripts

Primary Efficacy (Pivotal Data)

- ⦿ Cauchy E, Cheguillaume B, Chetaille E. A controlled trial of a prostacyclin and rt-PA in the treatment of severe frostbite. *N Engl J Med*. 2011;364(2):189-190. doi: 10.1056/NEJMc1000538
- ⦿ Cheguillaume, B. *Controlled trial of iloprost and iloprost and rt-PA in the treatment of severe frostbite*. Grenoble School of Medicine Thesis. Saint-Martin-d'Hères, France. HAL. 2011. <https://dumas.ccsd.cnrs.fr/dumas-00618697>

Observational Studies

- ⦿ Crooks S, Shaw BH, Andruchow JE, Lee CH, Walker I. Effectiveness of intravenous prostaglandin to reduce digital amputations from frostbite: an observational study. *CJEM*. 2022;24(6):622-629. doi: 10.1007/s43678-022-00342-9
- ⦿ Poole A, Gauthier J, MacLennan M. Management of severe frostbite with iloprost, alteplase and heparin: a Yukon case series. *CMAJ Open*. 2021;9(2):E585-E591. doi: 10.9778/cmajo.20200214

Iloprost Pharmacokinetics and Pharmacodynamics

- ⦿ Krause W, Kraus T. Pharmacokinetics and pharmacodynamics of the prostacyclin analogue iloprost in man. *Eur J Clin Pharmacol*. 1986;30(1):61-68. doi: 10.1007/BF00614197
- ⦿ Krause W, Kraus T. Pharmacokinetics and pharmacodynamics of radio-labeled iloprost in elderly volunteers. *Eur J Clin Pharmacol*. 1987;32(6):597-605. doi: 10.1007/BF02455995
- ⦿ Hildebrand M, Krause W, Angeli P, et al. Pharmacokinetics of iloprost in patients with hepatic dysfunction. *Int J Clin Pharmacol Ther Toxicol*. 1990;28(10):430-434. <https://pubmed.ncbi.nlm.nih.gov/1701761/>
- ⦿ Hildebrand M, Krause W, Fabian H, Koziol T, Neumayer H. Pharmacokinetics of iloprost in patients with chronic renal failure and on maintenance haemodialysis. *Int J Clin Pharmacol Res*. 1990;10(5):285-292. <https://pubmed.ncbi.nlm.nih.gov/1706685/>

Iloprost Case Reports and Case Series

- ⑤ Cauchy E, Davis CB, Pasquier M, Meyer EF, Hackett PH. A new proposal for management of severe frostbite in the austere environment. *Wilderness Environ Med.* 2016;27(1):92-99. doi: 10.1016/j.wem.2015.11.014
- ⑤ Gruber E, Oberhammer R, Brugger H, et al. Prolonged critical avalanche burial for nearly 23 h with severe hypothermia and severe frostbite with good recovery: a case report. *Scand J Trauma Resusc Emerg Med.* 2024;32(1):11. doi: 10.1186/s13049-024-01184-3
- ⑤ Magnan DM, Gelsomino M, Louge P, Pignel R. Successful delayed hyperbaric oxygen therapy and iloprost treatment on severe frostbite at high altitude. *High Alt Med Biol.* 2022;23(3):294-297. doi: 10.1089/ham.2021.0172
- ⑤ Magnan MA, Gayet-Ageron A, Louge P, et al. Hyperbaric oxygen therapy with iloprost improves digit salvage in severe frostbite compared to iloprost alone. *Medicina.* 2021;57(11):1284. doi: 10.3390/medicina57111284
- ⑤ Pandey P, Vadlamudi R, Pradhan R, Pandey KR, Kumar A, Hackett P. Case report: severe frostbite in extreme altitude climbers – the Kathmandu iloprost experience. *Wilderness Environ Med.* 2018;29(3):366-374. doi: 10.1016/j.wem.2018.03.003
- ⑤ Poole A, Gauthier J. Treatment of severe frostbite with iloprost in northern Canada. *CMAJ.* 2016;188(17-18):1255-1258. doi: 10.1503/cmaj.151252
- ⑤ Tam A, Lyons T, Vennam S, Barnes R, Imray C. Early use of iloprost in nonfreezing cold injury. *Wilderness Environ Med.* 2022;33(3):344-347. doi: 10.1016/j.wem.2022.04.009
- ⑤ Yiğit E, Yastı AÇ. Review of our 10 years experience in cold burns at the burn center in the Southeast Anatolia region of Turkey. *Ulus Travma Acil Cerrahi Derg.* 2022;28(3):369-374. doi: 10.14744/tjtes.2021.21901

Other Publications

Iloprost Reviews

- Ⓞ Gauthier J, Morris-Janzen D, Poole A. Iloprost for the treatment of frostbite: a scoping review. *Int J Circumpolar Health*. 2023;82(1):2189552. doi: 10.1080/22423982.2023.2189552
- Ⓞ Groechnenig E. Treatment of frostbite with iloprost. *Lancet*. 1994;344(8930):1152-1153. doi: 10.1016/s0140-6736(94)90657-2
- Ⓞ Lowe J, Warner M. Can iloprost be used for treatment of cold weather injury at the point of wounding in a forward operating environment? A literature review. *Int J Circumpolar Health*. 2023;82(1):2210340. doi: 10.1080/22423982.2023.2210340

Reviews That Include Iloprost for the Treatment of Frostbite

- Ⓞ Handford C, Thomas O, Imray CHE. Frostbite. *Emerg Med Clin North Am*. 2017;35(2):281-299. doi: 10.1016/j.emc.2016.12.006
- Ⓞ Lorentzen AK, Davis C, Penninga L. Interventions for frostbite injuries. *Cochrane Database Syst Rev*. 2020;12(12):CD012980. doi: 10.1002/14651858.CD012980.pub2
- Ⓞ Regli IB, Oberhammer R, Zafren K, Brugger H, Strapazzon G. Frostbite treatment: a systematic review with meta-analyses. *Scand J Trauma Resusc Emerg Med*. 2023;31(1):96. doi: 10.1186/s13049-023-01160-3
- Ⓞ Sheridan RL, Gerverman JM, Walker TG. Diagnosis and treatment of frostbite. *N Engl J Med*. 2022;386(23):2213-2220. doi: 10.1056/NEJMr1800868
- Ⓞ Zaramo TZ, Green JK, Janis JE. Practical review of the current management of frostbite injuries. *Plast Reconstr Surg Glob Open*. 2022;10(10):e4618. doi: 10.1097/GOX.0000000000004618

Abstracts

- Ⓞ Dow J. Cold injury. *Emerg Med Clin North Am*. 2024;42(3):513-525. doi: 10.1016/j.emc.2024.02.012
- Ⓞ Kaller M. BET 2: treatment of frostbite with iloprost. *Emerg Med J*. 2017;34(10):689-690. doi: 10.1136/emered-2017-207129.2
- Ⓞ Vampola CL, Fahrbach K, Huelin R, et al. Risk of amputation in severe frostbite—a systematic literature review and meta-analysis to evaluate iloprost and standard of care. *Wilderness Environ Med*. 2023;34(4):e4-e4. doi: 10.1016/j.wem.2023.08.016
- Ⓞ Yakaback S, Hartley R, Redwood J, et al. Defrosting the evidence: iloprost may reduce the amputation rate in severe frostbite injuries. Abstract presented at: Canadian Society of Plastic Surgeons 76th Annual Meeting; June 13-16, 2023; Whistler, BC. <https://plasticsurgery.ca/wp-content-csps/uploads/2023/06/CSPS-ABSTRACTS-2023.pdf>

Clinical Practice Guidelines/Clinical Protocols for the Treatment of Frostbite

- ⑤ AFP Editors. Frostbite: recommendations for prevention and treatment from the Wilderness Medical Society. *Am Fam Physician*. 2020;101(7):440-442. <https://www.aafp.org/pubs/afp/issues/2020/0401/p440.pdf>
- ⑤ Handford C, Buxton P, Russell K, et al. Frostbite: a practical approach to hospital management. *Extrem Physiol Med*. 2014;3:7. doi: 10.1186/2046-7648-3-7
- ⑤ Lindford A, Valtonen J, Hult M, et al. The evolution of the Helsinki frostbite management protocol. *Burns*. 2017;43(7):1455-1463. doi: 10.1016/j.burns.2017.04.016
- ⑤ McIntosh SE, Freer L, Grissom CK, et al. Wilderness Medical Society Clinical Practice Guidelines for the Prevention and Treatment of Frostbite: 2024 Update. *Wilderness Environ Med*. 2024;35(2):183-197. doi:10.1177/10806032231222359
- ⑤ Whitehorse frostbite protocol. Yukon Hospitals. Accessed January 22, 2025. https://yukon.ca/sites/default/files/whitehorse_frostbite_protocol_physicians_pre-printed_orders_revised_december_2020.pdf
- ⑤ Wibbenmeyer L, Lacey AM, Endorf FW, et al. American Burn Association Clinical Practice Guidelines on the Treatment of Severe Frostbite. *J Burn Care Res*. 2024;45(3):541-556. doi: 10.1093/jbcr/irad022

Indication and Important Safety Information

INDICATION AND USAGE

AURLUMYN is a prostacyclin mimetic indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations. Effectiveness was established in young, healthy adults who suffered frostbite at high altitudes.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- AURLUMYN may cause symptomatic hypotension. Correct hypotension prior to administration of AURLUMYN. Monitor vital signs while administering AURLUMYN.

Adverse Reactions

- Adverse events reported with the use of intravenous (IV) iloprost in patients with frostbite include headache, flushing, palpitations/tachycardia, nausea, vomiting, dizziness, and hypotension.

Use in Specific Populations

- Advise women not to breastfeed during treatment with AURLUMYN.
- The safety and efficacy of AURLUMYN in pediatric patients have not been established.
- Dosage adjustment is recommended in patients with moderate or severe hepatic impairment.
- In patients with eGFR <30 mL/min, dosage adjustment can be considered based on tolerability. The effect of dialysis on the clearance of AURLUMYN has not been evaluated.

To report suspected adverse reactions, contact us at 1-877-377-3784 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for full [Prescribing Information](#) for AURLUMYN.

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