SERB Pharmaceuticals

previously in the US as BTG Pharmaceuticals GLOBAL

First FDA-approved treatment for severe frostbite now commercially available in the US

09 December 2024

BACK TO NEWS

Philadelphia, 9 December 2024: SERB Pharmaceuticals, a global specialty pharmaceutical company, is proud to announce that Aurlumyn™ (iloprost) Injection, the first FDA-approved treatment for severe frostbite in adults to reduce the risk of digit amputations, is now commercially available in the US.[1]

Aurlumyn ™ is available through specialty distribution by FFF Enterprises Inc. Customers interested in ordering can call 1-800-843-7477 or visit https://biosupply.fffenterprises.com.

Aurlumyn™ will be formally launched during this week's American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting & Exhibition. ASHP meeting attendees can learn more about Aurlumyn ™ by visiting booth 339.

Dr. Jennifer Dow, Emergency Medicine physician at Alaska Regional Hospital and Medical Director for the Alaska Region of the National Park Service, said: "This marks a significant milestone in the field of frostbite treatment in the

Thomas Kolaras, Executive Vice President and US Chief Commercial Officer, said: “We are proud to make Aurlumyn™ available to hospitals, first responders, and military customers in the US. This treatment empowers healthcare professionals to act decisively in critical moments, delivering hope and effective care to those at risk of life-altering complications.”

Studies show that thousands of people are hospitalized with frostbite in the US each year.[2] This rare but highly debilitating condition most often affects winter sports enthusiasts, military personnel, outdoor workers, and the unhoused. Frostbite is a high morbidity, high-cost injury that can lead to digit or limb necrosis requiring amputation.[3] Aurlumyn™ is indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations.

The most recent Wilderness Medical Society Clinical Practice Guidelines for the Prevention and Treatment of Frostbite strongly recommends considering Aurlumyn™ as a first-line therapy for Grades 3 and 4 frostbite <48 hours after thawing, and possibly for up to 72 hours.

About SERB Pharmaceuticals

SERB is a global specialty pharmaceutical company with a growing portfolio of medicines for emergency care and rare diseases. For over 30 years we have made treating these complex and life-threatening conditions possible, supporting clinicians, healthcare systems and governments while offering hope to patients and their families. SERB is a leading provider of essential acute care medicines, addressing unmet medical needs and supplying antidotes and medical countermeasures for chemical, biological, radiological and nuclear (CBRN) risks. As a fully integrated company, we have the experience and capabilities to acquire, develop, and manufacture our medicines to the highest standards, and make them available worldwide through our secure supply chain.

Learn more at https://SERB.com

and orphan drug designation (ODD) and was approved by the FDA in February of 2024 for the treatment of severe frostbite in adults to reduce the risk of digit amputations. A published case series review showed that Aurlumyn™ can be effective up to 72 hours after rewarming of a frostbite patient begins.

Learn more at: https://aurlumyn.com/

For further information contact:
Chris Sampson, Director of Corporate Communications
chris.sampson@serb.com; Tel: +44 (0)7773 251 178

INDICATIONS 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.

• 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 BTG at 1-877-377-3784 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information.

US-AUR-2400046

1 Aurlumyn Prescribing Information

2 Endorf FW, Nygaard RM. Social Determinants of Poor Outcomes Following Frostbite Injury: A Study of the National Inpatient Sample. J Burn Care Res. 2021 Nov 24;42(6):1261-1265. doi: 10.1093/jbcr/irab115. PMID: 34139760.

3 Endorf FW, Nygaard RM. High Cost and Resource Utilization of Frostbite Readmissions in the United States. J Burn Care Res. 2021 Sep 30;42(5):857-864. doi: 10.1093/jbcr/irab076. PMID: 33993288.

4 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 Jan 13;364(2):189-90. doi: 10.1056/NEJMc1000538. PMID: 21226604.

BACK TO NEWS

Related news:

Newly published study shows that Voraxaze® can improve clinical outcomes in patients with high-dose methotrexate induced acute

previously in the US as BTG Pharmaceuticals

with acquisition of Aurlumyn™ (iloprost IV) for severe frostbite

FDA has accepted a BLA for bentracimab, the first and only ticagrelor reversal agent, for filing and priority review

Search site

This website is intended for a global audience.