

AURLUMYN™ (iloprost) Injection

AURLUMYN Ordering, Pricing, and Distribution Product Fact Sheet

AURLUMYN—the first and only FDA-approved treatment option for severe frostbite^{1,2}

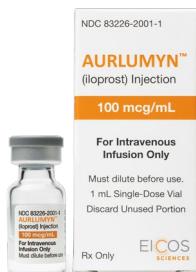
Established name: Iloprost injection, for intravenous use¹

Website: AURLUMYN.com

Supplied and marketed by: SERB Pharmaceuticals and BTG International Inc. | SERB.com

24-hour medical information: 1-877-377-3784 | serbmedinfo@serb.com

Customer service: 1-844-293-0007



IMPORTANT SAFETY INFORMATION

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.¹

Warnings and Precautions

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

Product information and pricing			
Product information	NDC number for ordering ¹	How supplied ¹	Sale quantity ¹
	11-digit Carton and Vial: 83226-2001-01 10-digit Carton and Vial: 83226-2001-1	Carton containing a clear, colorless sterile solution supplied as 100 mcg per mL in a single-dose glass vial.	1 vial (per carton)
Pricing	WAC ³ : \$5,500 per vial NOTE: AURLUMYN pricing as of November 12, 2024. Please confirm the current pricing with your SERB Representative.		

Ordering and distribution information	
Ordering information	AURLUMYN is available through specialty distribution. Please see the specialty distributor listed below.
Distribution	FFF Enterprises Inc. 1-800-843-7477 https://biosupply.fffenterprises.com

FDA, US Food and Drug Administration; NDC, National Drug Code; WAC, wholesale acquisition cost.

Please see Indications and Important Safety Information on page 3 and scan QR code on page 4 for full Prescribing Information for AURLUMYN.



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Key product and packaging information			
Dimensions and weight	Carton dimensions⁴	Package quantity¹	Carton weight⁴
	1.35 in x 1.40 in x 2.85 in	1 vial (per carton)	0.035 lb
Storage and handling	<ul style="list-style-type: none"> Unopened vials of AURLUMYN are stable until the date indicated on the package when stored at 20°C to 25°C (68°F to 77°F).¹ The unopened vial should be kept in the carton and not exposed to direct sunlight. Do not freeze.¹ 		
Expiration date and shelf life	AURLUMYN has a 30-month shelf life from the date of manufacture when stored at 20°C to 25°C (68°C to 77°C). ⁵ The expiration date is printed on each AURLUMYN carton.		
Dosage and administration	<p>Recommended dosing regimen Administer AURLUMYN as a continuous intravenous infusion over 6 hours each day for up to a maximum of 8 consecutive days.¹</p> <p>Dosage for patients with hepatic or renal impairment Dosage adjustment is recommended for patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) and may be necessary for patients with renal impairment with eGFR <30 mL/min. Dosage adjustment can be considered based on tolerability and should follow the guidance for these patient populations in Section 2.3 and Section 2.4 of the full AURLUMYN Prescribing Information.¹</p> <p>Key dilution considerations AURLUMYN should only be diluted using sterile 0.9% Sodium Chloride Injection, USP. Do not dilute or mix AURLUMYN with any other parenteral medications or solutions prior to or during administration.¹</p> <p>Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if visibly opaque particles, discoloration, or foreign particles are observed.¹</p> <p>Immediately use diluted AURLUMYN infusion solution. If not used immediately, the diluted solution can be stored at room temperature (20°C to 25°C [68°F to 77°F]) for up to 4 hours. Discard any unused portion.¹</p> <p>NOTE: These are not all the considerations and procedures for AURLUMYN dosage and administration. Please see full AURLUMYN Prescribing Information, Section 2.1, for more information.</p>		

Product and medical information support	
Product replacement	For questions regarding replacement, please contact Customer Service at: 1-844-293-0007.
Product information, adverse event reporting, and product complaints	For additional information about AURLUMYN, to report adverse events, or to file a product complaint, contact SERB Medical Information (available 24 hours). 1-877-377-3784 serbmedinfo@serb.com

eGFR, estimated glomerular filtration rate.

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Indications and Important Safety Information

INDICATIONS AND USAGE

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

References: **1.** AURLUMYN. Prescribing information. BTG International Inc.; 2024. https://aurlumyn.com/sites/aurlumyn-library/files/2024-11/PI_Aurlumyn_iloprost_label_May2024.pdf **2.** SERB Pharmaceuticals expands leading emergency care portfolio with acquisition of Aurlumyn™ (iloprost IV) for severe frostbite. News release. SERB Pharmaceuticals. October 21, 2024. Accessed October 30, 2024. <https://serb.com/news/serb-pharmaceuticals-expands-leading-emergency-care-portfolio-with-acquisition-of-aurlumyn-iloprost-iv-for-severe-frostbite/> **3.** Data on file. BTG Commercial Price List and Catalog. BTG International Inc.; 2024. **4.** Data on file. AURLUMYN carton dimensions and weight. BTG International Inc.; 2024. **5.** Data on file. Iloprost Injection for Intravenous Use New Drug Application 217933. Eicos Sciences Inc.; 2024.

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(iloprost) Injection



Please scan QR code for full
Prescribing Information for AURLUMYN.



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