USFDA approves first medication for severe frostbite treatment

The FDA granted the approval of Aurlumyn to Eicos Sciences Inc.

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February 16, 2024 09:30 IST

The U.S. Food and Drug Administration (USFDA) approved Aurlumyn (iloprost) injection to treat severe frostbite in adults to reduce the risk of finger or toe amputation.

“This approval provides patients with the first-ever treatment option for severe frostbite,” said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiology and Nephrology in the FDA’s Center for Drug Evaluation and Research. “Having this new option provides physicians with a tool that will help prevent the lifechanging amputation of one’s frostbitten fingers or toes.”

Frostbite can occur in several stages, ranging from mild frostbite that does not require medical intervention and does not cause permanent skin damage, to severe frostbite when both the skin and underlying tissue are frozen and blood flow is stopped, sometimes requiring amputation. Iloprost, the active ingredient in Aurlumyn, is a vasodilator (a drug that opens blood vessels) and prevents blood from clotting.

The most common side effects of Aurlumyn include headache, flushing, heart palpitations, fast heart rate, nausea, vomiting, dizziness, and hypotension (blood pressure that is too low). Aurlumyn also has a warning and precaution noting that it may cause symptomatic hypotension.

According to USFDA’s statement, Aurlumyn received Priority Review and Orphan Drug designations for this indication.

Iloprost was originally approved in 2004 for the treatment of pulmonary arterial hypertension. The FDA granted the approval of Aurlumyn to Eicos Sciences Inc.

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