FDA approves iloprost for severe frostbite

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Aurlumyn (iloprost), a vasodilator, has been approved by the U.S. Food and Drug Administration to treat severe frostbite. The injected medication lowers the risk for finger or toe amputation.

"This approval provides patients with the first-ever treatment option for severe frostbite," Norman Stockbridge, M.D., director of the Division of Cardiology and Nephrology in the FDA Center for Drug Evaluation and

Research, said in an agency news release. "Having this new option provides physicians with a tool that will help prevent the life-changing amputation of one's frostbitten fingers or toes."

The FDA approval hinged on the results of a trial that randomly assigned 47 adults with severe frostbite, all of whom received intravenous aspirin and standard of care, into one of three treatment groups.

Group 1 received Aurlumyn intravenously for six hours a day for up to eight days. The two other groups received other medications that are not approved for frostbite, given with Aurlumyn (group 2) or without Aurlumyn (group 3). The main measure of efficacy was a bone scan taken seven days after the initial frostbite that predicted the need for amputation of at least one finger or toe. None of the 16 patients receiving Aurlumyn alone was found to need amputation compared with 19 percent of patients in group 2 and 60 percent of patients in group 3.

The most common side effects with Aurlumyn included headache, flushing, heart palpitations, fast heart rate, nausea, vomiting, dizziness, and hypotension. Aurlumyn also carries a warning noting that it may cause symptomatic low hypotension, the FDA noted.

More information: FDA announcement