FDA NEWS RELEASE

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FDA approves new hand-held auto-injector to reverse opioid overdose

First naloxone treatment specifically designed to be given by family members or caregivers

The U.S. Food and Drug Administration today approved a prescription treatment that can be used by family members or caregivers to treat a person known or suspected to have had an opioid overdose. Evzio (naloxone hydrochloride injection) rapidly delivers a single dose of the drug naloxone via a hand-held auto-injector that can be carried in a pocket or stored in a medicine cabinet.

It is intended for the emergency treatment of known or suspected opioid overdose, characterized by decreased breathing or heart rates, or loss of consciousness.

Drug overdose deaths, driven largely by prescription drug overdose deaths, are now the leading cause of injury death in the United States – surpassing motor vehicle crashes. In 2013, the Centers for Disease Control and Prevention reported the number of drug overdose deaths had steadily increased for more than a decade.

Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for overdose. However, existing naloxone drugs require administration via syringe and are most commonly used by trained medical personnel in emergency departments and ambulances.

“Overdose and death resulting from misuse and abuse of both prescription and illicit opioids has become a major public health concern in the United States,” said Bob Rappaport, M.D., director of the Division of Anesthesia, Analgesia, and Addiction Products in the FDA’s Center for Drug Evaluation and Research. “Evzio is the first combination drug-device product designed to deliver a dose of naloxone for administration outside of a health care setting. Making this product available could save lives by facilitating earlier use of the drug in emergency situations.”

Evzio is injected into the muscle (intramuscular) or under the skin (subcutaneous). Once turned on, the device provides verbal instruction to the user describing how to deliver the medication, similar to automated defibrillators. Family members or caregivers should become familiar with all instructions for use before administering to known or suspected persons to have had an opioid overdose. Family members or caregivers should also become familiar with the steps for using Evzio and practice with the trainer device, which is included along with the delivery device, before it is needed.

Because naloxone may not work as long as opioids, repeat doses may be needed. Evzio is not a substitute for immediate medical care, and the person administering Evzio should seek further, immediate medical attention on the patient’s behalf.

In one pharmacokinetic study of 30 patients, a single Evzio injection provided equivalent naloxone compared to a single dose of naloxone injection using a standard syringe. The use of Evzio in patients who are opioid dependent may result in severe opioid withdrawal. Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, accelerated heart rate (tachycardia), increased blood pressure, uncontrollable trembling (tremulousness), seizures and cardiac arrest.

The FDA reviewed Evzio under the agency's priority review program, which provides for an expedited review of drugs that appear to provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products. The product was granted a fast-track designation, a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

Evzio is being approved ahead of the product's prescription drug user fee goal date of June 20, 2014, the date the agency was originally scheduled to complete review of the drug application.

Evzio's approval is also the result of efforts by several federal agencies. Naloxone has been a part of the White House's Office of National Drug Control Policy's National Drug Control Strategy since 2012. The FDA co-chairs an HHS inter-departmental working group on naloxone, which helped coordinate an April 12, 2012, meeting regarding access to naloxone products.

Evzio is manufactured for kaléo, Inc., of Richmond, Va.

For more information:

FDA: Approved Drugs
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm054420.htm

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