



NEWS RELEASE

Media Alert: Experts Available Now And At American College of Allergy, Asthma and Immunology (ACAAI) Scientific Meeting

10/31/2016

FDA Approved, Low-cost Treatment for Patients who Require Epinephrine Auto-Injection, Available Now
HAYWARD, Calif., Oct. 31, 2016 /PRNewswire/ --

WHAT: There is ongoing concern regarding price increases of pharmaceutical products. Impax (NASDAQ: IPXL), a long-standing and well-established generic drug provider, offers a FDA-approved, easy-to-use and effective **epinephrine auto-injector which delivers life-saving epinephrine at an affordable price.**

WHEN: Experts are available immediately and during the American College of Allergy, Asthma and Immunology (ACAAI) Scientific Meeting, to discuss Impax Epinephrine Auto-Injector as the GO-TO-CHOICE for affordable epinephrine for the emergency treatment of allergic reactions (Type I) including anaphylaxis.

WHERE: ACAAI will be held from November 10-14 at The Moscone Convention Center in San Francisco. All attendees are encouraged to visit the Impax booth (#331).

WHY: Every 3 minutes a food allergy reaction sends someone to the emergency department amounting to about 200,000 emergency department visits per year.i Food allergies are the leading cause of anaphylaxis outside of the hospital setting and the failure to treat anaphylaxis with epinephrine can lead to fatalities.ii iii Impax puts patients first, providing education, support, and financial assistance.

WHO: The following experts are available to speak with reporters about the use of Impax Epinephrine Auto-Injector as a proven, low-cost emergency treatment for patients who require epinephrine:

- Mark Donohue Vice President Investor Relations and Corporate Communications of Impax
- Dr. Sherron Kell Vice President Corporate Drug Safety & Medical Affairs of Impax (onsite interviews)

CONTACT: John Kouten, 609-241-7352, for more information or to schedule an interview.

Product fact sheet available [here](#).

About Epinephrine Injection, USP Auto-Injector

Important Safety Information

Indications and Usage

The epinephrine injection, USP auto-injector is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects and biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Warnings and Precautions

Emergency Treatment: The epinephrine injection, USP auto-injector is intended for immediate administration as emergency supportive therapy and is not intended as a substitute for immediate medical care. **In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care.** More than two sequential doses of epinephrine should only be administered under direct medical supervision.

Incorrect Locations of Injection: The epinephrine injection, USP auto-injector should **ONLY** be injected into the anterolateral aspect of the thigh. **Do not inject intravenously.** Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to a sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration. **Do not inject into buttock.** Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis. Injection into the buttock has been associated with the development of Clostridial infection (gas gangrene). Cleansing with alcohol does not kill bacterial spores, and therefore, does not lower the risk. **Do not inject into fingers, hands or feet.** Since epinephrine is a strong vasoconstrictor, accidental injection into the fingers, hands or feet may result in loss of blood flow to the affected area. Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration should consist of vasodilation, in addition to further appropriate treatment of anaphylaxis. **Hold leg firmly during injection.** Lacerations, bent needles, and embedded needles have been reported when epinephrine has been injected into the thigh of young children who are uncooperative and kick or move during an injection. To minimize the risk of injection related injury when

administering epinephrine injection, USP auto-injector to young children, instruct caregivers to hold the child's leg firmly in place and limit movement prior to and during injection.

Allergic Reactions Associated with Sulfite: The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

Serious Infections at the Injection Site: Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene), have been reported at the injection site following epinephrine injection for anaphylaxis. Clostridium spores can be present on the skin and introduced into the deep tissue with subcutaneous or intramuscular injection.

Disease Interactions: Some patients may be at greater risk for developing adverse reactions after epinephrine administration. **Patients with Heart Disease.** Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. **Other Patients and Diseases.** Epinephrine should be administered with caution to patients with hyperthyroidism, diabetes, elderly individuals, and pregnant women. Patients with Parkinson's disease may notice a temporary worsening of symptoms.

Adverse Reactions

Common adverse reactions to systemically administered epinephrine include anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache, and/or respiratory difficulties.

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease.

Accidental injection into the fingers, hands or feet may result in loss of blood flow to the affected area.

Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury.

Lacerations, bent needles, and embedded needles have been reported when epinephrine injection, USP auto-

injector has been injected into the thigh of young children who are uncooperative and kick or move during an injection.

Injection into the buttock has resulted in cases of gas gangrene.

Rare cases of serious skin and soft tissue infections caused by Clostridia (gas gangrene), have been reported following epinephrine injection in the thigh.

Use in Specific Populations

Elderly patients may be at greater of developing adverse reactions.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For full prescribing information and video instructions on the use of the epinephrine injection, USP auto-injector, go to www.epinephrineautoinject.com or call 1-888-894-6528.

About Impax Laboratories, Inc.

Impax Laboratories, Inc. (Impax) is a specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of central nervous system disorder branded products. Impax markets its generic products through its Impax Generics division and markets its branded products through its Impax Specialty Pharma division. Additionally, where strategically appropriate, Impax develops marketing partnerships to fully leverage its technology platforms and pursues partnership opportunities that offer alternative dosage form technologies, such as injectables, nasal sprays, inhalers, patches, creams and ointments. For more information, please visit the Company's Web site at: www.impaxlabs.com.

i Clark S, Espinola J, Rudders SA, Banerji, A, Camargo CA. Frequency of US emergency department visits for food-related acute allergic reactions. J Allergy ClinImmunol. 2011; 127(3): 682-683.

ii Sampson HA. Anaphylaxis and emergency treatment. J Pediatr.2004; 111: 1601-1608.

iii Bock SA, Muñoz-Furlong A, Sampson HA. Fatalities due to anaphylactic reactions to foods. J Allergy ClinImmunol.2001; 107(1): 191-3

Photo - <http://photos.prnewswire.com/prnh/20161031/434158>

PDF - http://origin-qps.onstreammedia.com/origin/multivu_archive/ENR/434159-Impax-Laboratories-Epinephrine-Auto-Injector-Fact-Sheet.pdf

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