

Important Safety Information for Epinephrine Injection, USP Auto-Injector:

Indications & 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 & 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 infections (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 risk of developing adverse reactions.

You are encouraged to report 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.

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