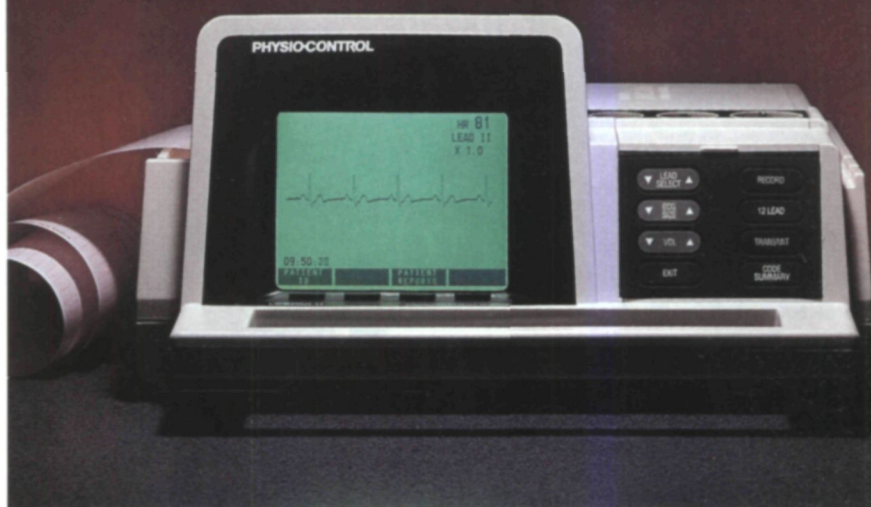
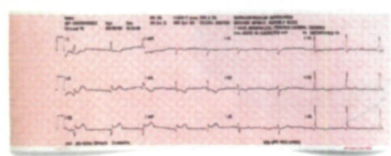


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There is only one Epinephrine Auto-Injector.

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Brief summary. Before prescribing, please consult package insert.

DESCRIPTION: The EpiPen Auto-Injector contains 2 mL epinephrine injector for emergency intramuscular use. Each EpiPen Auto-Injector delivers a single dose of 0.3 mg epinephrine from Epinephrine Injector, USP, 1:1000 (0.3 mg) in a sterile solution. Each EpiPen Jr. Auto-Injector delivers a single dose of 0.15 mg epinephrine from Epinephrine Injector, USP, 1:2000 (0.3 mg) in a sterile solution. Each 0.3 mg auto-injector contains 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.5 to 0.

CLINICAL PHARMACOLOGY: Epinephrine is a sympathomimetic drug acting on both alpha and beta receptors. It is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to insect stings or bites, foods, drugs, and other allergens. It can also be used for the treatment of idiopathic or exercise-induced anaphylaxis. Epinephrine when given subcutaneously or intramuscularly has a rapid onset and short duration of action.

INDICATIONS AND USAGE: Epinephrine is indicated in the emergency treatment of allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise-induced anaphylaxis. The EpiPen Auto-Injector is intended for immediate self-administration by a person with a history of an anaphylactic reaction. Such reactions may occur within minutes after exposure and consist of flushing, acute respiratory distress, tachycardia, intractable or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rash, urticaria or angioedema. The EpiPen is designed as emergency support for the physician and is not a replacement or substitute for immediate medical or hospital care.

CONTRAINDICATIONS: There are no absolute contraindications to the use of epinephrine in a life-threatening situation.

WARNINGS: Epinephrine injections (EpiPen) should be stored in the tube provided. Store at room temperature (15°-30°C/59°-86°F). Do not refrigerate. Before using, check to make sure solution in Auto-Injector is not discolored. Replace the Auto-Injector if the solution is discolored or contains a precipitate. Avoid possible inadvertent intravascular administration. Select an appropriate injection site such as the thigh. DO NOT INJECT INTO BUTTOCK. Large doses or accidental intravenous injection of epinephrine may result in cardiac arrhythmias due to sharp rise in blood pressure. DO NOT INJECT INTRAVENOUSLY. Rapidly acting vasoconstrictors can counteract the marked pressor effects of epinephrine.

Epinephrine is the preferred treatment for serious allergic or other emergency

situations even though this product contains sodium metabisulfite, a sulfite that may in other products cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations.

Accidental injection into the hands or feet may result in loss of blood flow to the affected area and should be avoided. If there is an accidental injection into these areas go immediately to the nearest emergency room for treatment. EpiPen should ONLY be injected into the intramuscular aspect of the thigh.

PRECAUTIONS: Epinephrine is ordinarily administered with extreme caution to patients who have heart disease. Use of epinephrine with drugs that may sensitize the heart to arrhythmias (e.g., digitalis, mercurial diuretics, or quinidine, ordinarily is not recommended. Angular pain may be induced by epinephrine in patients with coronary insufficiency. The effects of epinephrine may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors. Hypertensive individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, and children under 30 kg (66 lbs.) body weight may be theoretically at greater risk of developing adverse reactions after epinephrine administration. Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and in any other person who might be in a position to administer EpiPen or EpiPen Jr. to a patient experiencing anaphylaxis, should be carefully instructed in regard to the circumstances under which this life-saving medication should be used.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Studies of epinephrine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted.

USAGE IN PREGNANCY: Pregnancy Category C. Epinephrine has been shown to be teratogenic in rats when given in doses about 25 times the human dose. There are no adequate and well-controlled studies in pregnant women. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC USE: Epinephrine may be given safely to children at a dosage appropriate to body weight (see Dosage and Administration).

ADVERSE REACTIONS: Side effects of epinephrine may include palpitations, tachycardia, sweating, nausea and vomiting, respiratory difficulty, pallor, dizziness,

weakness, tremor, headache, apprehension, nervousness, and anxiety. Cardiac arrhythmias may follow administration of epinephrine.

OVERDOSAGE: Overdosage or inadvertent intravascular injection of epinephrine may cause cerebral hemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary edema because of peripheral vascular constriction together with cardiac stimulation.

DOSSAGE AND ADMINISTRATION: Usual epinephrine adult dose for allergic emergencies is 0.3 mg (1 or 2 injections) at the appropriate dosage may be 0.15 to 0.30 mg depending upon the body weight of the patient. However, the prescribing physician has the option of prescribing more or less than these amounts, based on careful assessment of each individual patient and recognizing the life-threatening nature of the reactions for which this drug is being prescribed. In severe cases of anaphylaxis, repeat injections with an additional EpiPen may be necessary.

HOW SUPPLIED: EpiPen and EpiPen Jr. Auto-Injectors are available singly or in packages of twelve.

CAUTION: Federal (U.S.A.) and provincial dispensing without a prescription. Issue: April 1997



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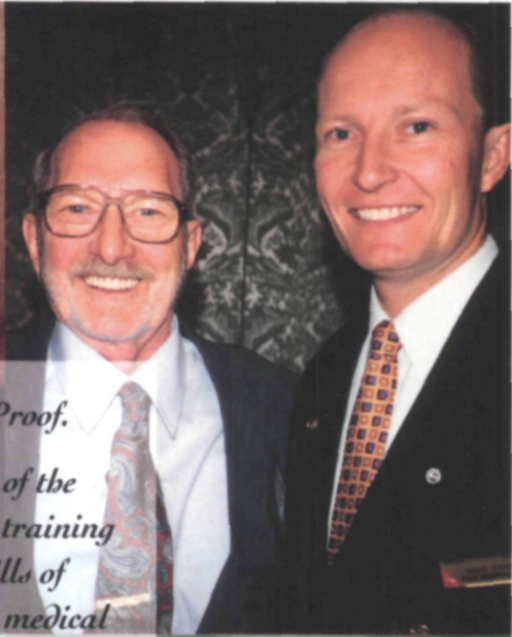
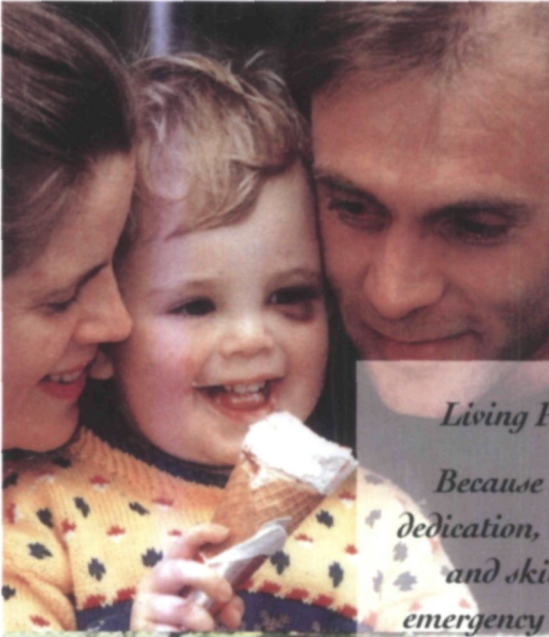


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Books—Schwartz GR, Safar P, Stone JH, et al, eds: *Principles and Practice of Emergency Medicine*. 2d ed. Philadelphia: W. B. Saunders Co., 1985, pp 1198-1202.
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Additional Information

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Annals of the Mediterranean Burns Club

Incorporating Fire Disasters

Official Organ of the Mediterranean Burns Club

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Editors **M. Masellis M.D.**

S.W.A. Gunn M.D.

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