# PRESCRIBING INFORMATION

## (PHARMACIST — PLEASE REMOVE BEFORE DISPENSING)

0907

**EPIPEN® 0.3 mg EPINEPHRINE AUTO-INJECTOR**
Auto-Injector for Intramuscular Injection of Epinephrine
For the Emergency Treatment of Allergic Reactions (Anaphylaxis)
Delivers a single 0.3 mg intramuscular dose of epinephrine from epinephrine injection, USP, 1:1000 (0.3 mL).

**EPIPEN® JR 0.15 mg EPINEPHRINE AUTO-INJECTOR**
Auto-Injector for Intramuscular Injection of Epinephrine
For the Emergency Treatment of Allergic Reactions (Anaphylaxis)
Delivers a single 0.15 mg intramuscular dose of epinephrine from epinephrine injection, USP, 1:2000 (0.3 mL).

**IMPORTANT INFORMATION**

- **DO NOT REMOVE ACTIVATION CAP UNTIL READY FOR USE.**
- **A SINGLE DOSE OF 0.3 ML OF SOLUTION IS DISPENSED. THE MAJORITY OF THE DRUG PRODUCT, 1.7 ML, REMAINS IN THE AUTO-INJECTOR AFTER ACTIVATION AND CANNOT BE USED.**
- **THE UNIT CONTAINS NO LATEX.**

### DESCRIPTION

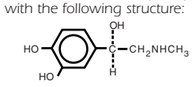
The EpiPen® and Epipen® Jr auto-injectors contain 2 mL epinephrine injection for emergency intramuscular use. Each EpiPen® auto-injector delivers ***a single dose*** of 0.3 mg epinephrine from epinephrine injection, USP, 1:1000 (0.3 mL) in a sterile solution.

Each EpiPen® Jr auto-injector delivers ***a single dose*** of 0.15 mg epinephrine from epinephrine injection, USP, 1:2000 (0.3 mL) in a sterile solution.

For stability purposes, approximately 1.7 mL remains in the auto-injector after activation and cannot be used.

Each 0.3 mL in EpiPen® contains 0.3 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0. Each 0.3 mL in EpiPen® Jr contains 0.15 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is B-(3, 4-dihydroxyphenyl)-a-methyl-aminoethanol, with the following structure:




It deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Epinephrine solutions which show evidence of discoloration should be replaced.

### 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 in the treatment of idiopathic or exercise-induced anaphylaxis. Epinephrine when given subcutaneously or intramuscularly has a rapid onset and short duration of action. The strong vasoconstrictor action of epinephrine through its effect on alpha adrenergic receptors acts quickly to counter vasodilation and increased vascular permeability which can lead to loss of intravascular fluid volume and hypotension during anaphylactic reactions. Epinephrine through its action on beta receptors on bronchial smooth muscle causes bronchial smooth muscle relaxation which alleviates wheezing and dyspnea. Epinephrine also alleviates pruritis, urticaria, and angioedema and may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis.

### 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® and EpiPen® Jr auto-injectors are 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, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritis, rashes, uticaria or angioedema. The EpiPen® and EpiPen® Jr are designed as emergency supportive therapy only and are 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 is light sensitive and 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 the solution in the auto-injector is not discolored. Replace the auto-injector if the solution is discolored or contains a precipitate. Avoid possible inadvertent intravascular administration. EpiPen® and EpiPen® Jr should **only** be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK.

Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. DO NOT INJECT INTRAVENOUSLY. Rapidly acting vasodilators 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, advise the patient to go immediately to the nearest emergency room for treatment. EpiPen® and EpiPen® Jr should **only** be injected into the anterolateral aspect of the thigh.

### PRECAUTIONS

Epinephrine is essential for the treatment of anaphylaxis. Patients with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens as well as idiopathic and exercise-induced anaphylaxis should be carefully instructed about the circumstances under which this life-saving medication should be used. It must be clearly determined that the patient is at risk of future anaphylaxis, since the following risks may be associated with epinephrine administration (see Dosage and Administration).

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. Anginal 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.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include: hyperthyroid individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, pediatric patients under 30 kg (66 lbs.) body weight using EpiPen®, and pediatric patients under 15 kg (33 lbs.) body weight using EpiPen® Jr.

Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and/or 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. This should not prevent the use of this life-saving medication under the conditions noted under INDICATIONS AND USAGE and as indicated under PRECAUTIONS above.

### 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 pediatric patients 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.

### DOSAGE AND ADMINISTRATION

A physician who prescribes EpiPen® or EpiPen® Jr should take appropriate steps to insure that the patient (or parent) understands the indications and use of this device thoroughly. The physician should review with the patient or any other person who might be in a position to administer EpiPen® or EpiPen® Jr to a patient experiencing anaphylaxis, in detail, the patient instructions and operation of the EpiPen® or EpiPen® Jr auto-injector. Inject the delivered dose of the EpiPen® auto-injector (0.3 mL epinephrine injection, USP, 1:1000) or the EpiPen® Jr auto injector (0.3mL epinephrine injection, USP, 1:2000) intramuscularly into the anterolateral aspect of the thigh, through clothing if necessary. See detailed Directions for Use on the accompanying Patient Instructions.

Usual epinephrine adult dose for allergic emergencies is 0.3 mg. For pediatric use, the appropriate dosage may be 0.15 or 0.30 mg depending upon the body weight of the patient. A dosage of 0.01 mg/kg body weight is recommended. EpiPen® Jr, which provides a dosage of 0.15 mg, may be more appropriate for patients weighing less than 30 kg. 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. The physician should consider using other forms of injectable epinephrine if doses lower than 0.15 mg are felt to be necessary.

Each EpiPen® or EpiPen® Jr contains a single dose of epinephrine. With severe persistent anaphylaxis, repeat injections with an additional EpiPen® may be necessary.

Parenteral drug products should be periodically inspected visually by the patient for particulate matter or discoloration and should be replaced if these are present.

### HOW SUPPLIED

EpiPen® auto-injectors (epinephrine injections, USP, 1:1000, 0.3 mL) are available in individual cartons, NDC 49502-500-01, and as EpiPen® 2-Pak™, a pack that contains two EpiPen® auto-injectors (epinehrine injections, USP, 1:1000, 0.3 mL) and one EpiPen® trainer device, NDC 49502-500-02.

EpiPen® Jr auto-injectors (epinephrine injection, USP, 1:2000, 0.3 mL) are available in individual cartons, NDC 49502-501-01, and as EpiPen® Jr 2-Pak™, a pack that contains two EpiPen® Jr auto-injectors (epinehrine injections, USP, 1:2000, 0.3 mL) and one EpiPen® trainer device, NDC 49502-501-02.

Store in a dark place at room temperature (15°-30°C/59°-86°F). Do not refrigerate. Contains no latex.

Rx only.

**MANUFACTURED FOR DEY, NAPA, CALIFORNIA, 94558, U.S.A.**
by Meridian Medical Technologies, Inc.,Columbia, MD 21046, U.S.A. 12/00 03-500-01

0000907.89496 Meridian Med. 12/7/00.G
Proof B 12/8/00.G Proof C 12/12/00 DES
Proof D 12/22/00.G