EPINEPHRINE 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)

EPINEPHRINE 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 UNIL 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-methylaminoethanamine, 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 as well as idiopathic or exercise-induced anaphylaxis. The Epipen® and Epipen® Jr 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, tachypnea or unstable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal edema, pruritis, rashes, urticaria 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 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 severe systemic 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 bee, 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, quinidine, quinidine, or quinidine, is not recommended. Arrhythmia 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: hyperthyroidism patients, patients 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. Fetal death may also result from primary 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 assure 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 (0.3 mL) epinephrine injection, USP 1:1000 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 49502-600-01, and as EpiPen® 2-Pak®, a package that contains two EpiPen® auto-injectors (epinephrine injections, USP 1:1000, 0.3 mL) and one EpiPen® Jr 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 package that contains two EpiPen® Jr auto-injectors (epinephrine injections, USP 1:2000, 0.3 mL) and one EpiPen® Jr trainer device, NDC 49502-501-02.

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

Rx only.
EpiPen® Jr 2-Pak™

(EPINEPHRINE) AUTO-INJECTORS
For Allergic Emergencies (Anaphylaxis)
0.15 mg each

EpiPen® Jr 2-Pak™ contains two EpiPen® Jr. auto-injectors and one trainer. Each EpiPen® Jr. auto-injector delivers one 0.15 mg intramuscular dose of epinephrine from epinephrine injection 1:2000 USP (0.3 mL). Discard unit after use. Trainer does not contain drug product or needle. Read enclosed patient package insert carefully before using.
For allergic emergencies (anaphylaxis)
EPIPen® Jr 2-Pak
0.15 mg each
For allergic emergencies (anaphylaxis)
EPIPen® AUTO-INJECTORS
EPIPen® Jr 2-Pak
NCI 49902-80102
EpiPen® Jr

0.15 mg EPINEPHRINE AUTO-INJECTOR
For Allergic Emergencies (Anaphylaxis)
Delivers 0.15 mg intramuscular dose of epinephrine from epinephrine injection 1:2000 (0.1 mL).

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

DIRECTIONS

1. Hold the grey cap on the injector
2. Swing the injector and hold firmly in your hand
3. As you squeeze the plunger, the needle will pierce the skin
4. Push the plunger all the way down
5. Hold firmly in place for 10 seconds

EpiPen® JR Trainer

Contains no drug product or needle.

DIRECTIONS FOR USE:

1. With the plunger out, swing the injector and hold firmly in your hand
2. As you squeeze the plunger, the needle will pierce the skin
3. Push the plunger all the way down
4. Hold firmly in place for 10 seconds

TO RESET: Place grey cap on flat hard surface and re-insert trainer over the stem until cap is reattached. DO NOT PUSH ON BLACK TIP.
**WARNING**

-- Never put thumb, fingers, or hand over black tip. Needle comes out of black tip. Accidental injection into hands or feet may result in loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room.
-- EpiPen®/EpiPen® Jr should be injected only into the outer thigh (see "Directions for Use").
-- Do NOT remove gray activation cap until ready to use.

**DIRECTIONS FOR USE**

--Follow these directions only when ready to use.
--Never put thumb, fingers, or hand over black tip.
--Do NOT remove gray activation cap until ready to use.

1) Familiarize yourself with the unit.

![Diagram of EpiPen®/EpiPen® Jr with clear window and gray activation cap]

2) Grasp unit, with the black tip pointing downward.
3) Form a fist around the auto-injector (black tip down).
4) With your other hand, pull off the gray activation cap.

5) Hold black tip near outer thigh.
6) Swing and jab firmly into outer thigh so that auto-injector is perpendicular (at a 90° angle) to the thigh.

7) Hold firmly in thigh for several seconds.

8) Remove unit, massage injection area for several seconds.
9) Check black tip:
   -- if needle is exposed, you received the dose
   -- if not, repeat steps 5-8
10) Note: most of the liquid (about 90%) stays in the auto-injector and cannot be reused.
11) Bend the needle back against a hard surface.
12) Carefully put the unit (needle first) back into the carrying tube (without the gray activation cap)
13) Recap the carrying tube.
14) See "Immediately After Use" box on right side.

**IMMEDIATELY AFTER USE**

-- Go immediately to the nearest hospital emergency room.
You may need further medical attention.
-- Tell the physician that you have received an injection of epinephrine (show your thigh).
-- Give your used EpiPen®/EpiPen® Jr to the physician for inspection and proper disposal.

MANUFACTURED FOR DEY, NAPA, CALIFORNIA 94558, U.S.A. by Meridian Medical Technologies, Inc. Columbia, MD 21045, U.S.A. U.S. Patent No. 4,031,693 03-335-00 12/00

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

ATTN: EpiPen®/EpiPen® Jr EXPIRATION REMINDER PROGRAM
PATIENT INSERT
(Pharmacist - Please dispense with product)

EpiPen* & EpiPen Jr
(epinephrine) Auto-Injectors
For allergic emergencies (anaphylaxis)

IMPORTANT INFORMATION
Both EpiPen* & EpiPen Jr
-- are disposable, prefilled automatic injection devices
-- are for allergic emergencies
-- contain a single dose of epinephrine (intramuscular)
-- are available by prescription only (Rx)
-- contain no latex

Amount of epinephrine delivered
EpiPen* = one dose of 0.30mg epinephrine (USP, 1:1000, 0.3mL)
EpiPen Jr = one dose of 0.15 mg epinephrine (USP, 1:2000, 0.3mL)
-- Note: most of the liquid (about 90%) stays in the auto-injector after use and cannot be reused

When to Use
Use the EpiPen*/EpiPen Jr auto-injector only if you are a hypersensitive (allergic) person and your doctor has prescribed it for allergic emergencies. Such emergencies may occur from insect stings or bites, foods, drugs, latex, other allergens, exercise-induced anaphylaxis, or unknown causes (idiopathic).

Emergency Treatment of Allergic Reaction (Anaphylaxis)
-- If you experience the signs and symptoms described by your physician:
-- Use the EpiPen*/EpiPen Jr auto-injector immediately, through clothing if necessary.
-- Repeat injection with an additional EpiPen* or EpiPen Jr may be necessary- consult your physician.
-- Follow "Directions for Use" section carefully.
-- Then follow steps in "Immediately After Use" section.
-- Avoid exertion.
-- If you have been stung by an insect:
-- Remove insect stinger with your fingernails if possible.
-- Do not squeeze, pinch, or push it deeper into the skin.
-- If available, apply ice packs or sodium bicarbonate soaks to the stung area.

Care & Storage
-- Keep the EpiPen*/EpiPen Jr auto-injector ready for use at all times.
-- Store:
-- in a dark place at room temperature (59-86°F)
-- plastic carrying tube provides added UV light protection
-- do NOT refrigerate
-- do NOT expose to extreme cold or heat
-- Note expiration date on the unit (month & year)
-- example: "Aug. 02" = Aug. 31, 2002
-- replace it before the expiration date
-- see below to enroll in the Expiration Reminder Program
-- always have at least one unexpired unit on hand
-- Examine contents in clear window of auto-injector periodically
-- replace the unit if the solution is discolored or contains solid particles (precipitate)
-- the physician may recommend emergency use of an auto-injector with discolored contents rather than to postpone treatment

Directions for Use (See reverse side)

EXPIRATION REMINDER PROGRAM

What to do
-- Replace your EpiPen*/EpiPen Jr prior to the expiration date on the unit
-- For your safety and convenience we will remind you when it is time to do so by enrolling in this free program
-- When you receive our expiration date notice, please return this card

Please PRINT clearly:
Name: ___________________________ Phone: ______________
Address: _________________________
City: _____________________________ State: ________ Zip: ________

Required:
On EpiPen*/EpiPen Jr: ___________ Expiration Date: ________

Please enter as written on unit: ___________ Lot #: ________

Optional:
_________________________ ____________________________
_________________________ ____________________________
_________________________ ____________________________
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