

Prescribing Information

EpiPen[®]

Sterile epinephrine injection USP

Unidose 0.3 mg epinephrine auto-injector

EpiPen[®] Jr

Sterile epinephrine injection USP

Unidose 0.15 mg epinephrine auto-injector

Catecholamine/ Sympatomimetic

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EpiPen®

Sterile epinephrine injection USP

EpiPen® Jr

Sterile epinephrine injection USP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Intramuscular Injection inject into anterolateral aspect of the thigh. Do not inject into the buttock.	EpiPen® Syringe, 1:1000 Unidose 0.3 mg epinephrine auto-injector EpiPen® Jr Syringe, 1:2000 Unidose 0.15 mg epinephrine auto-injector	hydrochloric acid sodium chloride sodium metabisulfite water for injection

INDICATIONS AND CLINICAL USE

EpiPen® (0.3 mL Epinephrine Injection, USP, 1:1000) and EpiPen® Jr (0.3 mL Epinephrine Injection, USP, 1:2000) are indicated for the emergency treatment of anaphylactic reactions in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight (see DOSAGE AND ADMINISTRATION section).

EpiPen® and EpiPen® Jr are intended for immediate self-administration for the emergency treatment of severe allergic reactions (Type I), including anaphylaxis associated with:

- foods (e.g., peanuts, tree nuts, shellfish, fish, milk, eggs, and wheat)
- stinging insects (e.g., Order Hymenoptera, including bees, wasps, hornets, yellow jackets, and fire ants) and biting insects (e.g., mosquitoes and black flies)
- medications

- latex
- idiopathic anaphylaxis
- exercise-induced anaphylaxis
- other allergens

Epinephrine is the drug of choice for the emergency treatment of severe allergic reactions. The strong vasoconstrictor action of epinephrine, through its effect on alpha adrenergic receptors, quickly counteracts vasodilation and increased vascular permeability which can lead to loss of intravascular fluid volume and hypotension during anaphylactic reactions.

EpiPen[®] and EpiPen[®] Jr are designed as emergency supportive therapy only and not as a replacement or substitute for subsequent medical or hospital care, nor are they intended to supplant insect venom hyposensitization.

Clinical Signs and Symptoms of Anaphylaxis

Anaphylaxis is a serious, acute, allergic reaction that may cause death¹. It has a sudden onset and generally lasts less than 24 hours. Because anaphylaxis is a generalized reaction, a wide variety of clinical signs and symptoms may be observed.

One to 2% of the general population are estimated to be at risk for anaphylaxis from food allergies and insect stings, with a lower reported prevalence for drugs and latex. People with asthma are at particular risk.

Symptoms of anaphylaxis may include:

Oral: pruritus of lips, tongue, and palate, edema of lips and tongue; metallic taste in the mouth.

Cutaneous: flushing, pruritus, urticaria, angioedema, morbilliform rash, and pilor erecti.

Gastrointestinal: nausea, abdominal pain, vomiting, and diarrhea.

Respiratory:

Laryngeal: pruritus and “tightness” in the throat, dysphagia, dysphonia, hoarseness, wheezing, and cough:

Nasal: nasal pruritus, congestion, rhinorrhea, sneezing, and sensation of itching in the external auditory canals.

Cardiovascular: feeling of faintness, syncope, chest pain, dysrhythmia, hypotension. **Note:** Hypotension is a sign of anaphylaxis. Patients should be treated in the early stages of anaphylaxis to prevent hypotension from developing.

Other: periorbital pruritus, erythema and edema, conjunctival erythema, and tearing; lower back pain and uterine contractions in women; aura of “doom.”

The severity of previous anaphylactic reactions does not determine the severity of future reactions, and subsequent reactions could be the same, better, or worse. The severity may depend on the degree of sensitivity, the dose of allergen, and other factors.

Research shows that fatalities from anaphylaxis are often associated with failure to use epinephrine or a delay in the use of epinephrine treatment.

Epinephrine should be administered as early as possible after the onset of symptoms of a severe allergic response. Patients requiring epinephrine will not always have predictable reactions. Adequate warning signs are not always present before serious reactions occur.

It is recommended that epinephrine be given at the start of any reaction associated with a known or suspected allergen contact. In patients with a history of severe cardiovascular collapse on exposure to an allergen, the physician may advise that epinephrine be administered immediately after exposure to that allergen, and before any reaction has begun.

Epinephrine may prove to be life saving when used as directed immediately following exposure to an allergen.

In most patients, epinephrine is effective after 1 injection. However, symptoms may recur and further injections may be required to control the reaction. Epinephrine can be re-injected every 5 to 15 minutes until there is resolution of the anaphylaxis or signs of adrenaline excess (such as palpitations, tremor, uncomfortable apprehension and anxiety).

All individuals receiving emergency epinephrine must be immediately transported to hospital, ideally by ambulance, for evaluation and observation. Repeat attacks have occurred hours later

without additional exposure to the offending allergen.²⁻⁴ Therefore, it is recommended that a patient suffering from an anaphylactic reaction be observed in an emergency facility for an appropriate period because of the possibility of either a “biphasic” reaction (a second reaction) or a prolonged reaction.⁴ At least a four hour period of observation is advised, although this time may vary. The attending physician will take into consideration such factors as the severity of the reaction, the patient’s response and history and the distance from the hospital to the patient’s home.

Anaphylactic reactions typically follow a uniphasic course; however, 20% will be biphasic in nature. The second phase usually occurs after an asymptomatic period of 1 to 8 hours, but may occur up to 38 hours (mean 10 hours) after the initial reaction. About one third of the second-phase reactions are more severe, one third are as severe, and one third are less severe. The second-phase reactions can occur even following administration of corticosteroids.

Following treatment of anaphylaxis, the patient must stay within close proximity to a hospital or where he or she can call 911 for the next 48 hours.

Protracted anaphylaxis, which is frequently associated with profound hypotension and sometimes lasts longer than 24 hours, is minimally responsive to aggressive therapy, and has a poor prognosis.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

General

Patients with a history of anaphylaxis are at risk for subsequent episodes and even death. All patients who have had one or more episodes of anaphylaxis should have injectable epinephrine with them or with their parent or caregiver at all times, and should wear some form of medical identification bracelet or necklace.

Following the resolution of an anaphylactic episode and discharge from hospital, the patient should immediately obtain and fill a new EpiPen[®] or EpiPen[®] Jr auto-injector prescription.

Epinephrine injection (1:1000 and 1:2000) is not intended as a substitute for medical attention or hospital care. In conjunction with the administration of epinephrine, the patient should seek appropriate medical care.

Antihistamines and asthma medications must not be used as first line treatment for an anaphylactic reaction.⁵

Accidental injection into the hands or feet may result in loss of blood flow to the affected areas and should be avoided. If there is an accidental injection into these areas, the patient must go immediately to the nearest emergency room for treatment. Epinephrine should only be injected into the anterolateral aspect of the thigh. Every effort should be made to avoid possible inadvertent intravascular administration through appropriate selection of an injection site such as the thigh. Do not inject into the buttock. 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.

The presence of a condition listed below is not a contraindication to epinephrine administration in an acute, life-threatening situation. Therefore, patients with these conditions, or any other person who might be in a position to administer epinephrine to a patient with these conditions experiencing anaphylaxis, should be instructed about the circumstances under which epinephrine should be used:

Cardiovascular

Epinephrine use should be avoided in patients with cardiogenic, traumatic, or hemorrhagic shock; cardiac dilation; and/or cerebral arteriosclerosis.

Epinephrine should be used with caution in patients with cardiac arrhythmias, coronary artery or organic heart disease, hypertension, or in patients who are on medications that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias.

Patients with hypertension or hyperthyroidism are prone to more severe or persistent effects.

Endocrine and Metabolism

Patients with diabetes may develop increased blood glucose levels following epinephrine administration.

Neurologic

Epinephrine use should be avoided in patients with organic brain damage.

Patients with Parkinson's disease may notice a temporary worsening of symptoms after treatment with epinephrine.

Ophthalmologic

Epinephrine use should be avoided in patients with narrow-angle glaucoma.

Respiratory

There is a significantly increased risk of respiratory symptoms in patients with concomitant asthma, especially if poorly controlled. These patients are at increased risk of death from anaphylaxis.

Fatalities may also occur from pulmonary edema resulting from peripheral constriction and cardiac stimulation.

Sensitivity

This product contains sodium metabisulfite, a substance which may cause allergic-type reactions including anaphylactic symptoms or mild to severe asthmatic episodes in certain susceptible persons.

Nevertheless, epinephrine is the drug of choice for serious allergic reactions and 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.

Reproduction

No studies have been conducted to determine epinephrine's potential effect on fertility.

Special Populations

Geriatrics (>65 years of age):

Elderly patients with hypertension, coronary artery disease or cardiac arrhythmias are particularly at risk for epinephrine overdose. More careful monitoring and avoidance of epinephrine overdose is recommended for these patients.

Pediatrics (patients 15-30 kg):

There are no data to suggest a difference in safety or effectiveness of epinephrine between adults and children in this weight group.

See [**DOSAGE AND ADMINISTRATION**](#) section for dosage requirements based on weight.

Pregnancy:

Although there are no adequate and well-controlled studies in pregnant women, epinephrine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse reactions of epinephrine include transient, moderate anxiety; feelings of over stimulation; apprehensiveness; restlessness; tremor; weakness; shakiness; dizziness; sweating; tachycardia; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. Ventricular arrhythmias may follow administration of epinephrine. While these symptoms occur in some patients treated with epinephrine, they are likely to be more pronounced in patients with hypertension or hyperthyroidism. These signs and symptoms usually subside rapidly, especially with bed rest.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include elderly individuals, pregnant women, and patients with diabetes.

Patients with coronary artery disease are prone to more severe or persistent effects, and may experience angina.

Excessive doses cause acute hypertension. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease.

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs (see [DRUG INTERACTIONS](#)).

The potential for epinephrine to produce these types of adverse reactions does not contraindicate its use in an acute life-threatening allergic reaction.

DRUG INTERACTIONS

Overview

There are no known contraindications to the use of epinephrine in a life-threatening allergic reaction.

Drug-Drug Interactions

Epinephrine should be used with caution in patients who are on medications that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias.

Caution is advised in patients receiving cardiac glycosides or diuretics, since these agents may sensitize the myocardium to beta-adrenergic stimulation and make cardiac arrhythmias more likely.

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, sodium levothyroxine, and certain antihistamines, notably chlorpheniramine, tripeleminamine, and diphenhydramine.

The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol. Anaphylaxis may be made worse by beta blockers because these drugs decrease the effectiveness of epinephrine.

The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine.

Phenothiazines may also reverse the pressor effects of epinephrine.

Deaths have been reported in asthmatic patients treated with epinephrine following the use of isoproterenol, orciprenaline, salbutamol, and long acting beta agonists.

Drug-Lifestyle Interactions

Cocaine sensitizes the heart to catecholamines (as does uncontrolled hyperthyroidism), and epinephrine use in these patients should be cautious.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Dosage in any specific patient should be based on body weight. A physician who prescribes EpiPen[®] or EpiPen[®] Jr should take appropriate steps to ensure that the patient thoroughly understands the indications and use of the device. The physician should review with the patient, in detail, the **CONSUMER INFORMATION** section and operation of the auto-injector.

EpiPen[®] and EpiPen[®] Jr contain 2 mL of solution but deliver a single dose of 0.3 mL **only**, with 1.7 mL remaining in the unit **after use**.

Inject only into the anterolateral aspect of the thigh.

Recommended Dose and Dosage Adjustment

EpiPen[®]:

EpiPen[®] delivers a dose of 0.3 mg in 0.3 mL of 1:1000 dilution of epinephrine injection, USP. EpiPen[®] is intended for adults and children who weigh 30 kg or more.

EpiPen[®] Jr:

EpiPen[®] Jr delivers a dose of 0.15 mg in 0.3 mL of 1:2000 dilution of epinephrine injection, USP. EpiPen[®] Jr is intended for children who weigh between 15 kg and 30 kg.

Since the dose of epinephrine delivered from EpiPen[®] Jr is fixed at 0.15 mg, the physician can consider other forms of injectable epinephrine if doses lower than 0.15 mg are felt to be necessary (e.g., for children weighing less than 15 kg).

Administration

Patients with a history of severe allergic reactions should be instructed about the circumstances under which epinephrine should be used (see [**INDICATIONS AND CLINICAL USE**](#) section).

The patient's physician or pharmacist should review the package insert in detail with the patient or caregiver to ensure that he/she understands the indications and use of EpiPen[®] or EpiPen[®] Jr.

Actual demonstration of the injection technique by a physician or a pharmacist is recommended. A training device for patient instruction purposes is also available.

EpiPen® and EpiPen® Jr are intended for intramuscular use in the anterolateral aspect of the thigh, through clothing if necessary. Do not inject into the buttock.

OVERDOSAGE

Epinephrine is rapidly inactivated in the body, and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be counteracted by rapidly acting vasodilators or alpha-adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug.

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Overdosage sometimes also results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations. Epinephrine overdosage can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol.

If an epinephrine overdose induces pulmonary edema that interferes with respiration, treatment consists of a rapidly acting alpha-adrenergic blocking drug and/or intermittent positive-pressure respiration.

Premature ventricular contractions may appear within 1 minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm).

Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block.

ACTION AND CLINICAL PHARMACOLOGY

Epinephrine acts on both alpha- and beta-adrenergic receptors. Through its action on alpha-adrenergic receptors, epinephrine counters the vasodilation and high vascular permeability that occurs during an anaphylactic reaction that can lead to loss of intravascular fluid volume and hypotension. Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation that helps alleviate bronchospasm, wheezing, and dyspnea that may occur during anaphylaxis.

Epinephrine also helps to alleviate pruritus, urticaria, and angioedema, and may be effective in relieving gastrointestinal and genitourinary symptoms of anaphylaxis because of its relaxant effects on the smooth muscle of the stomach, intestine, and urinary bladder. Epinephrine contracts the smooth muscle of the uterus.

Epinephrine, when given intramuscularly or subcutaneously, has a rapid onset and short duration of action.

STORAGE AND STABILITY

Always store EpiPen[®] or EpiPen[®] Jr in the carrier tube with the blue safety release on until you need to use it. Store at 25°C (77°F); EXCURSIONS PERMITTED TO 15° - 30°C (59 ° - 86°F). Do not refrigerate. Protect from light. Periodically check to make sure the solution in the auto-injector is not brown in color. Replace if it is discolored or contains a precipitate.

DOSAGE FORMS, COMPOSITION AND PACKAGING

EpiPen[®] and EpiPen[®] Jr are designed to be compact and easy to carry, and to provide emergency treatment when medical care is not immediately available.

Highly sensitive individuals should have epinephrine injectable products readily available at all times.

EpiPen[®]

Each auto-injector contains: 2 mL epinephrine injection 1:1000 and is designed to deliver a single dose of epinephrine 0.3 mg in 0.3 mL.

Nonmedicinal ingredients: Each mL contains: sodium chloride 6 mg, sodium metabisulfite 1.67 mg and hydrochloric acid to adjust pH. Contains no latex.

EpiPen[®] Jr

Each auto-injector contains: 2 mL epinephrine injection 1:2000 and is designed to deliver a single dose of epinephrine 0.15 mg in 0.3 mL.

Nonmedicinal ingredients: Each mL contains: sodium chloride 6 mg, sodium metabisulfite 1.67 mg and hydrochloric acid to adjust pH. Contains no latex.

PART II: SCIENTIFIC INFORMATION

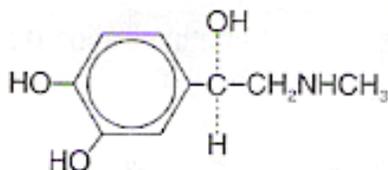
PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Epinephrine

Chemical name: 1-(3,4-dihydroxyphenyl)-2-(methylamino)ethanol

Structural formula:



Physicochemical properties: Epinephrine is a sympathomimetic catecholamine. Its naturally occurring *l*-isomer, which is twenty times as active as the *d*-isomer, is obtained in pure form by separation from the synthetically produced racemate.

REPRODUCTION

Teratogenic Effects. Pregnancy Category C

Epinephrine has been shown to have adverse developmental effects in rabbits at a subcutaneous dose of 1.2 mg/kg (approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis), in mice at a subcutaneous dose of 1 mg/kg (approximately 7 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis), and in hamsters at a subcutaneous dose of 0.5 mg/kg (approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis).

These effects were not seen in mice at a subcutaneous dose of 0.5 mg/kg (approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis).

REFERENCES

1. Sampson H. et al. Second Symposium on the Definition and Management of Anaphylaxis: Summary Report – Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network Symposium. *Journal of Allergy and Clinical Immunology* 2006; 117(2) 391-397.
2. Stark BJ, Sullivan TJ. Biphasic and protracted anaphylaxis. *Journal of Allergy and Clinical Immunology* 1986; 78:76-83.
3. Lieberman P. Biphasic Anaphylaxis (Review) *Allergy and Clinical Immunology International – Journal of the World Allergy Organization* 2004;16:241-248.
4. Sampson HA. Anaphylaxis and Emergency Treatment. *Pediatrics* 2003;111;1601-1608

5. Allen, M. et al. (2005) Anaphylaxis in Schools and Other Settings, Hamilton, Ontario: Canadian Society of Allergy and Clinical Immunology.

PART III: CONSUMER INFORMATION

EpiPen[®]
Sterile epinephrine injection USP
Unidose 0.3 mg epinephrine auto-injector

EpiPen[®] Jr
Sterile epinephrine injection USP
Unidose 0.15 mg epinephrine auto-injector

This leaflet is Part III of a three-part “Prescribing Information” document published when EpiPen[®], EpiPen[®] Jr were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EpiPen[®], EpiPen[®] Jr. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

EpiPen[®] and EpiPen[®] Jr are indicated for the emergency treatment of anaphylaxis and are intended for people determined to be at risk for serious allergic reactions and for people with a history of anaphylactic reactions.

EpiPen[®] and EpiPen[®] Jr should be used immediately to treat yourself or your child when experiencing a severe allergic reaction. This is emergency treatment. It does not replace seeing a doctor or going to the hospital.

Anaphylaxis is the term for a severe, life-threatening allergic reaction that some people have to foods (like peanuts and shellfish), insect stings, certain medicines, latex, or other allergens. These reactions can also be triggered by exercise or even by unknown causes. A severe allergic reaction occurs when a person is exposed to an allergen (an allergy-causing substance). When the allergen enters the body it triggers the releases of chemicals that can lead to life-threatening symptoms.

Those who are considered to be at a higher risk of anaphylaxis include people:

- who have previously experienced allergic reactions or anaphylaxis
- who suffer from asthma
- who have food allergies

Anaphylaxis affects multiple body systems: skin, upper and lower respiratory system, intestinal tract, heart and blood vessels.

The most common warning symptoms of anaphylaxis are:

- Hives and swelling

Typical symptoms of anaphylaxis include:

- Swelling of the throat, lips, tongue, or the area around the eyes
- Difficulty breathing or swallowing
- Metallic taste or itching in the mouth
- Generalized flushing, itching, or redness of the skin
- Stomach cramps, nausea, vomiting, or diarrhea
- Increased heart rate

- Decreased blood pressure
- Paleness
- Sudden feeling of weakness
- Anxiety or an overwhelming sense of doom
- Collapse
- Loss of consciousness

What it does:

EpiPen[®] and EpiPen[®] Jr contain epinephrine, which is the medication that helps to decrease your body’s allergic reaction. Some of the ways it works include:

- Relaxing the muscles in your airways so you can breathe more easily
- Helping to reverse the rapid and dangerous decrease in blood pressure
- Relaxing the muscles in your stomach, intestines, and bladder

What the medicinal ingredient is:

Epinephrine.

What the nonmedicinal ingredients are:

Hydrochloric acid, sodium chloride, sodium metabisulfite, and water for injection.

What dosage forms it comes in:

EpiPen[®]: Unidose 0.3 mg epinephrine auto-injector

EpiPen[®] Jr: Unidose 0.15 mg epinephrine auto-injector

EpiPen[®] and EpiPen[®] Jr come in disposable, prefilled automatic injection devices.

WARNINGS AND PRECAUTIONS

If you have had one or more episodes of anaphylaxis you (or your parent or caregiver) should carry EpiPen[®] or EpiPen[®] Jr at all times. You should also wear some form of medical identification bracelet or necklace.

EpiPen[®] and EpiPen[®] Jr are not intended as a substitute for medical attention or hospital care. After you use EpiPen[®] or EpiPen[®] Jr, always seek medical care immediately.

BEFORE you obtain EpiPen[®] or EpiPen[®] Jr, talk to your doctor or pharmacist about all of your medical conditions, especially if you have:

- heart disease, irregular heartbeat, or high blood pressure
- diabetes
- thyroid conditions
- narrow-angle glaucoma
- depression or other mental disease
- Parkinson's disease
- asthma
- previously had an allergic reaction
- An allergy to any of the ingredients in this medication
- Also notify your doctor and pharmacist if you are pregnant or breast feeding

EpiPen® or EpiPen® Jr remains the essential treatment for anaphylaxis even if you have the above conditions.

EpiPen® or EpiPen® Jr should not be injected into the hands or feet as this may result in the loss of blood flow to the affected areas. If you accidentally inject into these areas, go immediately to the nearest emergency room for treatment.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with EpiPen® or EpiPen® Jr include:

- Heart rhythm medicine, such as digoxin or quinidine (another name for digoxin is digitalis)
- Diuretic medicines ("water pills")
- MAO inhibitors (MAOI), such as selegiline, isocarboxazid, phenelzine sulfate, or tranylcypromine
- Tricyclic antidepressants, such as amitriptyline, doxepin, nortriptyline
- Antihistamines, such as chlorpheniramine, tripeleminamine, or diphenhydramine
- Beta-adrenergic blocking drugs, such as propranolol
- Alpha-adrenergic blocking drugs, such as phentolamine
- Ergot alkaloids and phenothiazines
- Isoproterenol, orciprenaline, salbutamol and LABAs
- Thyroid medications (e.g. sodium levothyroxine)
- Cocaine

PROPER USE OF THIS MEDICATION

If you have been told by your doctor that you are at risk for an anaphylactic reaction, carry your EpiPen® or EpiPen® Jr with you at all times.

IMPORTANT NOTE: Anaphylaxis can result in death if not treated immediately. Talk to your doctor about the warning signs and symptoms of anaphylaxis and when to use EpiPen® or EpiPen® Jr. In addition, if you experience any of the symptoms of anaphylaxis listed in the "ABOUT THIS MEDICATION" section, you should administer EpiPen® or EpiPen® Jr IMMEDIATELY and then seek immediate transport to hospital, ideally by ambulance, where you will remain under observation and receive additional treatment, as

required. If symptoms persist while awaiting transport to the hospital, administer another dose of EpiPen® or EpiPen® Jr.

Usual dose:

EpiPen®, (0.3 mg) should be used for adults and children weighing 30 kg or more. EpiPen® Jr (0.15 mg) should be used for children weighing between 15 kg to 30 kg. For children weighing less than 15 kg, call 911.

Directions for Use

Caution

- Remove EpiPen® or EpiPen® Jr from carrier tube before use
- Never put thumb, fingers or hand over orange tip
- Never press or push orange tip with thumb, fingers, or hand
- The injection needle comes out of orange tip
- Do not remove blue safety cap until ready to use
- Remove blue safety cap by pulling straight up (*Do not bend or twist off the blue safety cap*)

To Take EpiPen® or EpiPen® Jr out of the Carrier Tube

- Flip open the cap on the carrier tube. The cap is yellow on EpiPen®, green on EpiPen® Jr.

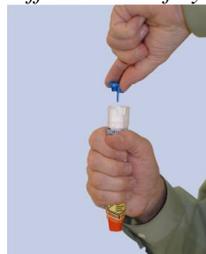


- Tip the carrier tube and slide EpiPen® or EpiPen® Jr out of the tube.



To Use EpiPen® or EpiPen® Jr

- Grasp EpiPen® or EpiPen® Jr with the orange tip pointing downward, form a fist around the unit (orange tip down), remove blue safety cap by pulling straight up. (*Do not bend or twist off the blue safety cap.*)



- Swing and push orange tip firmly into outer thigh so it “clicks” AND HOLD on thigh for several seconds. Inject even through clothing if necessary. Do not inject EpiPen® or EpiPen® Jr into your hands, feet, or buttock.



- Remove EpiPen® or EpiPen® Jr from the thigh. Massage the injected area if desired. **Note:** The orange needle cover automatically extends to cover the injection needle when EpiPen® or EpiPen® Jr is removed from the thigh.



- The injection is now complete.
- Seek medical attention immediately even if the severe allergy symptoms seem to have subsided. Because the effects of epinephrine can wear off and there is a chance of a second reaction, **it is important that you seek medical assistance or go to the emergency room immediately after using EpiPen® or EpiPen® Jr.**
- Even if you have sought medical help, you must stay within close proximity to a hospital or where you can easily call 911 for the next 48 hours.**

The used EpiPen® or EpiPen® Jr with extended orange needle cover will not fit back into the carrier. Give any used EpiPen® or EpiPen® Jr to emergency responders or emergency room personnel.

Overdose:

Too much epinephrine can cause dangerously high blood pressure, stroke, or death.

If you take more than the recommended dose, or inject the EpiPen® or EpiPen® Jr anywhere other than your thigh, go to the nearest emergency room for treatment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

EpiPen® and EpiPen® Jr are intended to be used immediately to treat yourself or your child when suffering from a severe allergic reaction. This is emergency treatment.

After you use EpiPen® or EpiPen® Jr always seek appropriate medical care. EpiPen® or EpiPen® Jr does not replace seeing a doctor or going to the hospital.

The following side effects may occur after using EpiPen® or EpiPen® Jr.

SERIOUS SIDE EFFECTS

Symptom / effect
Difficulty breathing
Increased heart rate (pounding heart)
Irregular or skipped heart beats
Angina (chest pain) or stroke (symptoms may include blurred vision, difficulty speaking, headache, dizziness, weakness)

Other potential side effects include:

- Paleness
- Dizziness
- Weakness
- Shaking
- Headache
- Throbbing
- Restlessness
- Anxiety
- Tenseness
- Fear

This is not a complete list of side effects.

It is important that you seek medical assistance or go to the emergency room immediately after using EpiPen® or EpiPen® Jr.

HOW TO STORE IT

- Keep your EpiPen® or EpiPen® Jr at room temperature. Do not refrigerate. Do not drop.
- Do not expose your EpiPen® or EpiPen® Jr to direct sunlight.
- Do not keep your EpiPen® or EpiPen® Jr in a vehicle during extremely hot or cold weather.
- Always keep your EpiPen® or EpiPen® Jr in the carrier tube with the blue safety cap on until you need to use it.
- Occasionally inspect your EpiPen® or EpiPen® Jr solution through the viewing window. Replace your EpiPen® or EpiPen® Jr if it is discolored or contains solid particles (precipitate) or if there are any signs of leakage. The solution should be clear.
- Discard if there are any signs of damage to the carrier or the EpiPen® or EpiPen® Jr.
- Do not attempt to take the EpiPen® or EpiPen® Jr apart.
- Replace your EpiPen® or EpiPen® Jr before the expiration date or after you use it.

- Talk to your pharmacist or physician about how to properly dispose of your expired EpiPen[®] or EpiPen[®] Jr.
- Do not place this Consumer Information or any other objects in the carrier tube with your EpiPen[®] or EpiPen[®] Jr, as this may prevent you from removing your EpiPen[®] or EpiPen[®] Jr, quickly for use.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

Patients may also register the expiration date of their EpiPen[®], EpiPen[®] Jr at www.EpiPen.ca. Shortly before this emergency care product expires, patients will be notified by E-mail or text message that the product is nearing expiry and should be replaced.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.EpiPen.ca or by contacting Pfizer Canada Inc. 1-877-EPIPEN 1 (1-877-374-7361).

This leaflet was prepared by Dey Pharma, L.P.

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