

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SYMJEP<sup>TM</sup> safely and effectively. See full prescribing information for SYMJEP<sup>TM</sup>.

**SYMJEPI<sup>TM</sup> (epinephrine) injection, for intramuscular or subcutaneous use**

Initial U.S. Approval: 1939

### INDICATIONS AND USAGE

SYMJEPI contains epinephrine, a non-selective alpha and beta-adrenergic receptor agonist, indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis. (1)

### DOSAGE AND ADMINISTRATION

Patients greater than or equal to 30 kg (66 lbs): Inject SYMJEP intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each pre-filled syringe is for a single injection. (2)

### DOSAGE FORMS AND STRENGTHS

Injection: single-dose, pre-filled syringe for manual injection containing 0.3 mg/0.3 mL epinephrine sterile solution for injection, USP (3)

### CONTRAINDICATIONS

None. (4)

### WARNINGS AND PRECAUTIONS

- In conjunction with use, seek immediate medical or hospital care (5.1)
- Do not inject intravenously, into buttock, or into digits, hands or feet. (5.2)
- To minimize the risk of injection-related injury, instruct caregivers to hold the child's leg firmly in place and limit movement prior to and during injection when administering to young children. (5.2)

- Rare cases of serious skin and soft tissue infections have been reported following epinephrine injection. Advise patients to seek medical care if they develop signs or symptoms of infection at the epinephrine injection site. (5.3)
- The presence of a sulfite in this product should not deter use. (5.4)
- Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5.5)

### ADVERSE REACTIONS

- Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Adamis Pharmaceuticals Corporation at 1-858-997-2400 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG INTERACTIONS

- Cardiac glycosides or diuretics: observe for development of cardiac arrhythmias. (7)
- Tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines: potentiate effects of epinephrine. (7)
- Beta-adrenergic blocking drugs: antagonize cardiostimulating and bronchodilating effects of epinephrine. (7)
- Alpha-adrenergic blocking drugs: antagonize vasoconstricting and hypertensive effects of epinephrine. (7)
- Ergot alkaloids: may reverse the pressor effects of epinephrine. (7)

### USE IN SPECIFIC POPULATIONS

Elderly patients may be at greater risk of developing adverse reactions. (5.5, 8.5)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

SYMJEPI is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

SYMJEPI is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic 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, pruritus, rashes, urticaria or angioedema.

SYMJEPI is intended for immediate administration as emergency supportive therapy only and is not a substitute for immediate medical care.

### **2 DOSAGE AND ADMINISTRATION**

This product delivers 0.3 mg epinephrine injection (0.3 mL) and is intended for patients who weigh 30 kg or more (approximately 66 pounds or more).

Inject SYMJEPI intramuscularly or subcutaneously into the anterolateral aspect of the thigh with the needle facing downwards. It can be injected through clothing if necessary. Instruct caregivers of young children who are prescribed SYMJEPI and who may be uncooperative and kick or move during an injection to hold the leg firmly in place and limit movement prior to and during an injection [see *Warnings and Precautions* (5.2)].

Each SYMJEPI contains a single dose of epinephrine for single-use injection. Since the doses of Epinephrine delivered from SYMJEPI are fixed, consider using other forms of injectable epinephrine if doses lower than 0.3 mg are deemed necessary.

The prescriber should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is indicated. With severe persistent anaphylaxis, repeat injections with an additional SYMJEPI may be necessary. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see *Warnings and Precautions* (5.1)].

SYMJEPI prescribers should ensure that the patient or caregiver is instructed and understands the indications and use of this product. A health care provider should review the patient instructions for SYMJEPI, in detail, with the patient or caregiver. Patients and/or any other person who might be in a position to administer an epinephrine injection should be advised of the proper site for injection and given appropriate instructions about imbedding the needle before transferring the thumb to the syringe plunger [see *Instructions for Use*].

The epinephrine solution in the syringe should be inspected visually for particulate matter and discoloration. Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light [see *How Supplied/Storage and Handling* (16.2)].

### **3 DOSAGE FORMS AND STRENGTHS**

Injection: Single-dose pre-filled syringe for manual injection, containing 0.3 mg/0.3 mL epinephrine sterile solution for injection, USP

### **4 CONTRAINDICATIONS**

None.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Emergency Treatment

SYMJEPI 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 [see *Indications and Usage (1)*, *Dosage and Administration (2)* and *Patient Counseling Information (17.1)*].

### 5.2 Injection-related Complications

SYMJEPI should **only** be injected into the anterolateral aspect of the thigh [see *Dosage and Administration (2)* and *Patient Counseling Information (17)*].

- Do not inject intravenously. Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to 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. Additionally, injection into the buttock has been associated with gas gangrene. Cleansing with alcohol does not kill bacterial spores and therefore, does not lower the risk.
- Do not inject into digits, hands or feet. Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, 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 [see *Adverse Reactions (6)*].
- **Hold leg firmly during injection.** To minimize the risk of injection related injury when administering SYMJEPI to young children, instruct caregivers to hold child's leg firmly in place and limit movement prior to and during injection.

### 5.3 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. While cleansing with alcohol may reduce presence of bacteria on the skin, alcohol cleansing does not kill Clostridium spores. To decrease the risk of Clostridium infection, do not inject SYMJEPI into the buttock [see *Warnings and Precautions (5.2)*]. Advise patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness, at the epinephrine injection site.

### 5.4 Allergic Reactions Associated with Sulfite

The presence of a sulfite in this product should not deter administration of the drug for the treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

Epinephrine is the preferred treatment for serious allergic reactions 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.

### 5.5 Disease Interactions

Some patients may be at greater risk for developing adverse reactions after epinephrine administration. Despite these concerns, it should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation.

Therefore, patients with these conditions, and/or any other person who might be in a position to administer SYMJEPI to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which epinephrine should be used.

- 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 [see *Drug Interactions (7) and Adverse Reactions (6)*].
- 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.

## **6 ADVERSE REACTIONS**

Due to the lack of randomized, controlled clinical trials of epinephrine for the treatment of anaphylaxis, the true incidence of adverse reactions associated with the systemic use of epinephrine is difficult to determine. Adverse reactions reported in observational trials, case reports and studies are listed below. 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. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism [see *Warnings and Precautions (5.5)*].

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs [see *Warnings and Precautions (5.5) and Drug Interactions (7)*].

Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease [see *Warnings and Precautions (5.5)*].

Angina may occur in patients with coronary artery disease [see *Warnings and Precautions (5.5)*].

Rare cases of stress cardiomyopathy have been reported in patients treated with epinephrine.

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area [see *Warnings and Precautions (5.2)*].

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.

Injection into the buttock has resulted in cases of gas gangrene [see *Warnings and Precautions (5.2)*].

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 in the thigh [see *Warnings and Precautions (5.2)*].

## **7 DRUG INTERACTIONS**

Patients who receive epinephrine while concomitantly taking cardiac glycosides, diuretics, or anti-arrhythmics should be observed carefully for the development of cardiac arrhythmias [see *Warnings and Precautions (5.4)*].

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, 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.

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

Ergot alkaloids may also reverse the pressor effects of epinephrine.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

There are no adequate and well controlled studies of the acute effect of epinephrine in pregnant women. In animal reproductive studies, epinephrine administered by the subcutaneous route to rabbits, mice, and hamsters during the period of organogenesis was teratogenic at doses 7 times and higher than the maximum recommended human intramuscular and subcutaneous dose on a mg/m<sup>2</sup> basis. Epinephrine is the first-line medication of choice for the treatment of anaphylaxis during pregnancy in humans. Epinephrine should be used for treatment of anaphylaxis during pregnancy in the same manner as it is used in non-pregnant patients.

In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and of miscarriage is 15-20%, respectively.

#### Clinical Considerations

##### *Disease-associated maternal and embryo/fetal risk:*

During pregnancy, anaphylaxis can be catastrophic and can lead to hypoxic-ischemic encephalopathy and permanent central nervous system damage or death in the mother and, more commonly, in the fetus or neonate. The prevalence of anaphylaxis occurring during pregnancy is reported to be approximately 3 cases per 100,000 deliveries.

Management of anaphylaxis during pregnancy is similar to management in the general population. Epinephrine is the first line-medication of choice for treatment of anaphylaxis; it should be used in the same manner in pregnant and non-pregnant patients. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care.

#### Data

##### Animal Data

In an embryofetal development study with rabbits dosed during the period of organogenesis, epinephrine was shown to be teratogenic (including gastroschisis and embryonic lethality) at doses approximately 40 times the maximum recommended intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at a maternal subcutaneous dose of 1.2 mg/kg/day for two to three days).

In an embryofetal development study with mice dosed during the period of organogenesis, epinephrine was shown to be teratogenic (including embryonic lethality) at doses approximately 8 times the maximum recommended intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at maternal subcutaneous dose of 1 mg/kg/day for 10 days). These effects were not seen in mice at approximately 4 times the maximum recommended daily intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

In an embryofetal development study with hamsters dosed during the period of organogenesis from gestation days 7 to 10, epinephrine was shown to be teratogenic at doses approximately 7 times the maximum recommended intramuscular or subcutaneous dose (on a mg/m<sup>2</sup> basis at a maternal subcutaneous dose of 0.5 mg/kg/day).

### **8.2 Lactation**

#### Risk Summary

There is no information regarding the presence of epinephrine in human milk, the effects on breastfed infants, or the effects on milk production. Epinephrine is the first line-medication of choice for treatment of anaphylaxis; it should be used in the same manner in breastfeeding and non-breastfeeding patients.

## 8.4 Pediatric Use

SYMJEPI may be given safely to pediatric patients at a dosage appropriate to body weight [see *Dosage and Administration (2)*]. Clinical experience with the use of epinephrine suggests that the adverse reactions seen in children are similar in nature and extent to those both expected and reported in adults. Since the dose of epinephrine delivered from SYMJEPI is fixed, consider using other forms of injectable epinephrine if a dose lower than 0.3mg is deemed necessary.

## 8.5 Geriatric Use

Clinical studies for the treatment of anaphylaxis have not been performed in subjects aged 65 and over to determine whether they respond differently from younger subjects. However, other reported clinical experience with use of epinephrine for the treatment of anaphylaxis has identified that geriatric patients may be particularly sensitive to the effects of epinephrine. Therefore, SYMJEPI should be administered with caution in elderly individuals, who may be at greater risk for developing adverse reactions after epinephrine administration. [see *Warnings and Precautions (5.4)*, *Overdosage (10)*].

## 10 OVERDOSAGE

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Overdosage may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Treatment consists of rapidly acting vasodilators or alpha-adrenergic blocking drugs and/or respiratory support.

Epinephrine overdosage can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one 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. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol.

Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations.

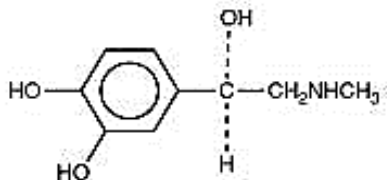
## 11 DESCRIPTION

Each SYMJEPI pre-filled, syringe delivers a single dose of 0.3 mg of epinephrine from epinephrine injection, USP (0.3mg/0.3 mL).

Each SYMJEPI (epinephrine injection, USP) syringe contains 0.8 mL of sterile aqueous solution of epinephrine for intramuscular or subcutaneous administration. The syringe is overfilled for stability purposes; more than half of the solution remains in the syringe after use and CANNOT BE REUSED.

Each 0.3 mL 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.

Epinephrine is a sympathomimetic catecholamine (a non-selective alpha and beta-adrenergic receptor agonist) designated chemically as (-)-3,4-Dihydroxy- $\alpha$ -[(methylamino)methyl]benzyl alcohol and has the following structure:



The molecular weight of epinephrine is 183.20.

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from formation of melanin. Replace SYMJEPI if the solution appears discolored (pinkish or brown color), cloudy, or contains particles.

## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**

Epinephrine acts on both alpha and beta-adrenergic receptors.

### **12.2 Pharmacodynamics**

Through its action on alpha-adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension.

Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation and helps alleviate bronchospasm, wheezing and dyspnea that may occur during anaphylaxis.

Epinephrine also alleviates pruritus, urticaria, and angioedema and may relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxer effects on the smooth muscle of the stomach, intestine, uterus and urinary bladder.

When given subcutaneously or intramuscularly, epinephrine has a rapid onset and short duration of action.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies to evaluate the carcinogenic potential of epinephrine have not been conducted.

Epinephrine and other catecholamines have been shown to have mutagenic potential *in vitro*. Epinephrine was positive in the *Salmonella* bacterial reverse mutation assay, positive in the mouse lymphoma assay, and negative in the *in vivo* micronucleus assay. Epinephrine is an oxidative mutagen based on the *E. coli* WP2 Mutoxitest bacterial reverse mutation assay. This should not prevent the use of epinephrine under the conditions noted under *Indications and Usage (1)*.

The potential for epinephrine to impair reproductive performance has not been evaluated, but epinephrine has been shown to decrease implantation in female rabbits dosed subcutaneously with 1.2 mg/kg/day (40-fold the highest human intramuscular or subcutaneous daily dose) during gestation days 3 to 9.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **16.1 How Supplied**

SYMJEPI (epinephrine injection, USP) 0.3 mg pre-filled syringes are available as a single pack, NDC 38739-200-01 containing a single pre-filled syringe, and as a two-pack, NDC 38739-200-02, a pack that contains 2 pre-filled syringes.

### **16.2 Storage and Handling**

Protect from light. Epinephrine is light sensitive and should be stored in the case provided to protect it from light. Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature). Do not refrigerate. Before using, check to make sure the solution in the syringe is clear and colorless. Replace the product if the solution is discolored (pinkish or brown color), cloudy, or contains particles. Used SYMJEPI should be given to a healthcare provider or emergency room personnel for proper disposal. Expired or discolored SYMJEPI should be returned to a healthcare provider or pharmacy for proper disposal.

## **17 PATIENT COUNSELING INFORMATION**

[see FDA-Approved Patient Labeling (*Patient Information and Instructions for Use*)]

A healthcare provider should review the patient instructions and operation of SYMJEPI, in detail, with the patient or caregiver.

Epinephrine is essential for the treatment of anaphylaxis. Patients who are at risk of or have 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 epinephrine should be used.

### **Administration and Training**

Instruct patients and/or caregivers in the appropriate use of SYMJEPi. SYMJEPi should be injected into the middle of the outer thigh (through clothing, if necessary). Each syringe is for a single-use injection. Advise patients to seek immediate medical care in conjunction with administration of SYMJEPi.

Young children may be uncooperative and kick or move during and injection. Instruct caregivers of young children who are prescribed SYMJEPi to hold the leg firmly in place and limit movement prior to and during an injection [see *Warnings and Precautions (5.2)*].

Complete patient information, including dosage, directions for proper administration and precautions can be found inside each SYMJEPi carton. A printed label on the surface of the SYMJEPi case shows instructions for use.

### **Adverse Reactions**

Epinephrine may produce symptoms and signs that include an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These signs and symptoms usually subside rapidly, especially with rest, quiet and recumbency. Patients with hypertension or hyperthyroidism may develop more severe or persistent effects, and patients with coronary artery disease could experience angina. Patients with diabetes may develop increased blood glucose levels following epinephrine administration. Patients with Parkinson's disease may notice a temporary worsening of symptoms. [see *Warnings and Precautions (5.4)*].

### **Accidental Injection**

Advise patients to seek immediate medical care in the case of accidental injection. Since epinephrine is a strong vasoconstrictor when injected into the digits, hands, or feet, treatment should be directed at vasodilatation if there is such an accidental injection to these areas [see *Warnings and Precautions (5.2)*].

### **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. Advise patients to seek medical care if they develop signs or symptoms of infection, such as persistent redness, warmth, swelling, or tenderness, at the epinephrine injection site [see *Warnings and Precautions (5.3)*].

### **Storage and Handling**

Instruct patients to inspect the epinephrine solution visually periodically. SYMJEPi should be replaced if the epinephrine solution appears discolored (pinkish or brown color), cloudy, or contains particles. Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Instruct patients that SYMJEPi must be used or properly disposed once the protective cap covering the needle is removed [see *How Supplied/Storage and Handling (16.2)*]. Instruct patients to give a used SYMJEPi syringe to their healthcare provider or emergency room personnel for proper disposal, and to return expired or discolored SYMJEPi to their healthcare provider or pharmacy for proper disposal.

Complete patient information, including dosage, directions for proper administration and precautions can be found inside each SYMJEPi case.

Manufactured for Adamis Pharmaceuticals Corporation. San Diego, CA