Meet Auvi-Q

A Breakthrough in Epinephrine Auto-Injector Design
This presentation is intended to:

- Provide a brief review of anaphylaxis definition, epidemiology, and management
- Describe current state of the anaphylaxis market
- Introduce Auvi-Q™ (epinephrine injection, USP) and its features
- Review key elements of Auvi-Q and anaphylaxis resources

**Indication**

- Auvi-Q™ (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens, idiopathic and exercise-induced anaphylaxis. Auvi-Q is intended for individuals with a history of anaphylaxis or who are at risk for anaphylactic reactions.

**Important Safety Information**

- Auvi-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical or hospital care.

Please see accompanying full Prescribing Information.
Anaphylaxis: Definition and Epidemiology

- Anaphylaxis is a serious allergic reaction that is rapid in onset and may cause death\(^1\)
- Up to 6 million people in the US are at risk for anaphylaxis\(^2,3\)
- The prevalence of anaphylaxis is rising, particularly among those under 20\(^3-9\)

### Causes of Anaphylaxis Cases (N=211)\(^4\)

- Food: 33%
- Insects: 19%
- Other: 9%
- Medications: 14%
- Unknown: 25%
- Contrast agent: 0.5%

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The Prevalence of Anaphylaxis Is on the Rise

8% Of Children Had A Food Allergy
In a 2009-2010 survey of US households, data collected for 38,480 children indicated that 8% – 1 in 12 – had a food allergy. 3.1% had a history of severe reactions, including anaphylaxis.¹

18% Increase In The Prevalence Of Food Allergies
According to a 2007 National Health Interview Survey, the prevalence of food allergy increased 18% from 1997 to 2007 among children younger than 18.²

4x Increase In Hospitalization Rate For Anaphylaxis
In New York State, from 1990 to 2006, the hospitalization rate for anaphylaxis among patients younger than 20 increased more than 4-fold (N=1972).³

2 Large Surveys* Showed That Most At-Risk Patients Do Not Always Carry An Epinephrine Auto-Injector

**Important Safety Information**
Epinephrine should be administered with caution to patients with certain heart diseases, and in patients who are on medications that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics.

*Surveys: Adults at risk for anaphylaxis and caregivers of at-risk children answered online surveys in November 2010 (n=600) and July 2011 (n=651). Participants must have filled and/or refilled an EAI prescription within the previous 36 months.

Data on file. sanofi-aventis Pharmaceuticals, Inc.
Anaphylaxis Emergency Action Plan: Key Elements

1. **Education for patient and family**
   - Allergen avoidance
   - Familiarity with anaphylaxis symptoms and the need to act quickly

2. **Anaphylaxis emergency plan**
   - Prescription for epinephrine auto-injector
   - Specifies use of epinephrine

3. **Medical alert jewelry or identification**
   - Bracelet or wallet card
   - Should state anaphylaxis diagnosis, other conditions and medications

4. **Follow-up**
   - Allergist/immunologist for additional testing

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**Important Safety Information**
- Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

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Epinephrine Is an Essential Medication in Anaphylaxis Treatment

**Immediate Management**
1. **Epinephrine is the only recognized first-line treatment**
   - Remove exposure to trigger
   - Assess airway, breathing, circulation, mental status
   - Administer epinephrine – repeat if necessary
   - Position patient on his/her back, elevate legs

**Subsequent Emergency Management**
1. **Antihistamines, corticosteroids, and/or bronchodilators may help manage symptoms**
   - Assess need for establishing airway, oxygen, and/or IV fluid administration
   - Consider use of inhaled bronchodilators, antihistamine, and/or corticosteroids

**Follow-Up Care**
1. **Includes provision of an epinephrine auto-injector and an emergency plan**
   - Avoidance of allergens
   - Epinephrine auto-injector
   - Emergency action plan
   - Referral to allergist

**Important Safety Information**
- Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.

A Breakthrough in Epinephrine Auto-Injector Design: Auvi-Q™ (epinephrine injection, USP)

For Patients at Risk for Life-Threatening Allergic Reactions

Indication
Auvi-Q™ (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens, idiopathic and exercise induced anaphylaxis. Auvi-Q is intended for individuals with a history of anaphylaxis or who are at risk for anaphylactic reactions.

Important Safety Information
Auvi-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical or hospital care.

Please see accompanying full Prescribing Information.
Meet Auvi-Q™ (epinephrine injection, USP)

**Important Safety Information**
- Auvi-Q should **ONLY** be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY.

Please see accompanying full Prescribing Information.
How To Use Auvi-Q™ (epinephrine injection, USP)

**Important Safety Information**

Epinephrine should be administered with caution to patients with certain heart diseases, and in patients who are on medications that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics.

Please see accompanying full Prescribing Information.

To view the video demonstration, please visit [www.auvi-q.com/hcp/view-demonstration-videos](http://www.auvi-q.com/hcp/view-demonstration-videos)
Auvi-Q™ (epinephrine injection, USP): Compact Size and Shape

All items shown in relative scale.
The Auvi-Q™ (epinephrine injection, USP) Trainer: A Key Patient Education Tool

- The Auvi-Q Trainer allows patients and caregivers to practice how to use an active Auvi-Q device before an emergency happens
- Will be provided as part of every prescription; available to HCPs for patient education
- Designed to be distinguishable from the active device to avoid patient confusion
- Mimics the Auvi-Q experience, including audio and visual cues
- Designed to be reused by patients and caregivers for training purposes

Important Safety Information
- Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.

Please see accompanying full Prescribing Information.
Auvi-Q™ (epinephrine injection, USP)  
And Anaphylaxis Resources

Auvi-Q offers helpful tools and resources. To download, visit: www.auvi-q.com/hcp

Important Safety Information
Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

Please see accompanying full Prescribing Information.
Summary

Auvi-Q™ (epinephrine injection, USP), For Individuals At Risk For Life-Threatening Allergic Reactions

- Audio & visual cues that guide users through the injection process
- “Press-and-hold” action with 5-second hold time
- Retractable needle mechanism designed to help prevent accidental needle sticks
- Unique compact size & shape
- Each Auvi-Q pack provides two 0.15 mg or 0.3 mg single-dose devices, a training device, and helpful patient information

Indication
- Auvi-Q™ (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens, idiopathic and exercise-induced anaphylaxis. Auvi-Q is intended for individuals with a history of anaphylaxis or who are at risk for anaphylactic reactions.

Important Safety Information
- Auvi-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical or hospital care.

Please see accompanying full Prescribing Information.
Indication

Auvi-Q™ (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens, idiopathic and exercise-induced anaphylaxis. Auvi-Q is intended for individuals with a history of anaphylaxis or who are at risk for anaphylactic reactions.

Important Safety Information

Auvi-Q should **ONLY** be injected into the anterolateral aspect of the thigh. **DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY.**

Epinephrine should be administered with caution to patients with certain heart diseases, and in patients who are on medications that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics. Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions. Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

Auvi-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical or hospital care.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information.
INDICATIONS AND USAGE

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

DOSE AND ADMINISTRATION

- Patients greater than or equal to 30 kg (66 lbs): Auvi-Q™ 0.3 mg (2)
- Patients 15 to 30 kg (33 lbs – 66 lbs): Auvi-Q™ 0.15 mg (2)

Inject Auvi-Q™ intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection. (2)

DOSE FORMS AND STRENGTHS

- Injection, 0.3 mg: 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector (3)
- Injection, 0.15 mg: 0.15 mg/0.15 mL epinephrine injection, USP, pre-filled auto-injector (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Do not inject intravenously, into buttock, or into digits, hands, or feet. (5,2)

ADVERSE REACTIONS

- The presence of a sulfite in this product should not deter use. (5,3)
- Administer with caution in patients with heart disease; may aggravate angina pectoris or produce ventricular arrhythmias. (5,4)

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)

DRUG INTERACTIONS

- Cardiac glycosides or diuretics: observe for development of cardiac arrhythmias. (7)
- Triyclic antidepressants, mocarnine oxdate inhibitors, levodopa, or dopamine, and certain antihistamines: potentiate effects of epinephrine. (7)
- Beta-adrenergic blocking drugs: antagonize cardio stimulating 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)

DRUG INTERACTIONS

- Beta-adrenergic blocking drugs: antagonize cardio stimulating 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)

INFORMATION (17.1)

- Do not inject into digits, hands or feet. (5,2)

PATIENT COUNSELING INFORMATION

- Elderly patients may be at greater risk of developing adverse reactions. (5,4, 8,5)

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Auvi-Q™ 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., triatomia, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Auvi-Q™ 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, purpura, rash, urticaria or angioedema. Auvi-Q™ is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care.

2 DOSAGE AND ADMINISTRATION

Selection of the appropriate dosage strength (Auvi-Q™ 0.3 mg or Auvi-Q™ 0.15 mg) is determined according to patient body weight.

- Patients greater than or equal to 30 kg (approximately 66 pounds or more): Auvi-Q™ 0.3 mg
- Patients 15 to 30 kg (33 lbs – 66 lbs): Auvi-Q™ 0.15 mg

Inject Auvi-Q™ intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each Auvi-Q™ contains a single dose of epinephrine for single-use injection. Since the doses of epinephrine delivered from Auvi-Q™ are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 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 Auvi-Q™ may be necessary. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see WARNINGS AND PRECAUTIONS (5.1)].

The epinephrine solution in the viewing window of Auvi-Q™ 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 STORAGE AND HANDLING (16.2)].

3 DOSAGE FORMS AND STRENGTHS

- Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector
- Injection, 0.15 mg/0.15 mL epinephrine injection, USP, pre-filled auto-injector

4 CONTRAINDICATIONS

None (4)

5 WARNINGS AND PRECAUTIONS

5.1 EMERGENCY TREATMENT

Auvi-Q™ 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 INCORRECT LOCATIONS OF INJECTION

Auvi-Q™ should only be injected into the anterolateral aspect of the thigh [see DOSAGE AND ADMINISTRATION (2) and PATIENT COUNSELING INFORMATION (17.1)].

- 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 vasoconstrictors can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.

5.3 ALLERGIC REACTIONS ASSOCIATED WITH SULFITE

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium bisulfite, 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.

6 ADVERSE REACTIONS

Severe persistent anaphylaxis, repeat injections with an additional Auvi-Q™ may be necessary. More than two sequential doses of epinephrine should only be administered under direct medical supervision [see WARNINGS AND PRECAUTIONS (5.1)].
The presence of a sulfite in this product should not deter administration of the drug for treatment of allergy or anaphylaxis because the amount of sulfite in Auvi-Q™ (epinephrine injection, USP) 0.3 mg and 0.15 mg is not to be considered a preservative. The sulfite is present to serve as a stabilizer of the product.

11. DESCRIPTION

Epinephrine injection, USP, 0.3 mg and 0.15 mg is an auto-injector and a combination of epinephrine injection, USP, 3 mg/mL in a sterile solution and a rapid injection system. The rapid injection system consists of a needle and plunger and is designed to deliver the epinephrine to the patient's circulation. The plunger can be actuated by using the “click” mechanism of the auto-injector. The device is designed to be used by the patient or caregiver.

Epinephrine injection, USP is not made with natural rubber latex.

Epinephrine acts on both alpha and beta-adrenergic receptors.

12. PHARMACODYNAMICS

Epinephrine is a potent vasoconstrictor and vasopressor and acts through multiple pharmacological mechanisms.

12.1 MECHANISM OF ACTION

Epinephrine acts on all adrenergic receptors.

12.2 PHARMACODYNAMICS

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light.

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 relaxant 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 and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay.

Epinephrine was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

The potential for epinephrine to impair fertility has not been evaluated.

This should not prevent the use of epinephrine under the conditions noted under INDIcATIONS AND USAGE (1).

16. HOW SUPPLIED/STORAGE AND HANDLING

This product contains two Auvi-Q™ (epinephrine injection, USP) 0.3 mg auto-injectors and a single Auvi-Q™ Trainer - NDC 0024-5835-02.

Carton containing two Auvi-Q™ (epinephrine injection, USP) 0.15 mg auto-injectors and a single Auvi-Q™ Trainer - NDC 0024-5831-02.

Rx only.

16.2 STORAGE AND HANDLING

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Store at 20–25°C (68–77°F); excursions permitted to 15–30°C (59–86°F). Do not refrigerate. Before using, check to make sure the solution in the auto-injector is clear and colorless. Replace the auto-injector if the solution is discolored, cloudy, or contains particles.

17. PATIENT COUNSELING INFORMATION

[see FDA-Approved Patient Labeling]

A healthcare provider should review the patient instructions and operation of Auvi-Q™, in detail, with the patient or caregiver.

Epinephrine is the primary treatment of anaphylaxis. Patients who are at risk of or with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergies, as well as idiopathic and exercise-induced anaphylaxis, should be carefully instructed about the circumstances under which epinephrine should be used.

17.1 ADMINISTRATION AND TRAINING

Patients and/or caregivers should be instructed in the appropriate use of Auvi-Q™. Auvi-Q™ should be injected into the middle of the outer thigh (through clothing, if necessary). Each device is a single-use disposable. Patients should seek immediate medical care in conjunction with administration of Auvi-Q™. Complete patient information, including dosage, directions for proper administration and precautions can be found inside each Auvi-Q™ carton. A printed label on the surface of Auvi-Q™ shows instructions for use and a diagram depicting the injection process. Auvi-Q™ also emits visual prompts and electronic voice instructions for use.

18. ADVERSE REACTIONS

Adverse reactions to 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 (5.4)). Epinephrine is a potent vasoconstrictor and vasopressor and acts through multiple pharmacological mechanisms.

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 relaxant 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 and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay.

Epinephrine was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

The potential for epinephrine to impair fertility has not been evaluated.

This should not prevent the use of epinephrine under the conditions noted under INDIcATIONS AND USAGE (1).

16. HOW SUPPLIED/STORAGE AND HANDLING

This product contains two Auvi-Q™ (epinephrine injection, USP) 0.3 mg auto-injectors and a single Auvi-Q™ Trainer - NDC 0024-5835-02.

Carton containing two Auvi-Q™ (epinephrine injection, USP) 0.15 mg auto-injectors and a single Auvi-Q™ Trainer - NDC 0024-5831-02.

Rx only.

16.2 STORAGE AND HANDLING

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Store at 20–25°C (68–77°F); excursions permitted to 15–30°C (59–86°F). Do not refrigerate. Before using, check to make sure the solution in the auto-injector is clear and colorless. Replace the auto-injector if the solution is discolored, cloudy, or contains particles.

17. PATIENT COUNSELING INFORMATION

[see FDA-Approved Patient Labeling]

A healthcare provider should review the patient instructions and operation of Auvi-Q™, in detail, with the patient or caregiver.

Epinephrine is the primary treatment of anaphylaxis. Patients who are at risk of or with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergies, as well as idiopathic and exercise-induced anaphylaxis, should be carefully instructed about the circumstances under which epinephrine should be used.

17.1 ADMINISTRATION AND TRAINING

Patients and/or caregivers should be instructed in the appropriate use of Auvi-Q™. Auvi-Q™ should be injected into the middle of the outer thigh (through clothing, if necessary). Each device is a single-use disposable. Patients should seek immediate medical care in conjunction with administration of Auvi-Q™. Complete patient information, including dosage, directions for proper administration and precautions can be found inside each Auvi-Q™ carton. A printed label on the surface of Auvi-Q™ shows instructions for use and a diagram depicting the injection process. Auvi-Q™ also emits visual prompts and electronic voice instructions for use.
Patients and/or caregivers should be instructed to use the Trainer to familiarize themselves with the use of Auvi-Q™ in an allergic emergency. The Trainer may be used multiple times.

17.2 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 symptoms and signs 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)].

17.3 ACCIDENTAL INJECTION

Patients should be advised 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)].

17.4 STORAGE AND HANDLING

Patients should be instructed to inspect the epinephrine solution visually through the viewing window periodically. Auvi-Q™ should be replaced if the epinephrine solution appears discolored (pinkish color or darker than slightly yellow), cloudy, or contains particles. Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Patients should be instructed that Auvi-Q™ must be used or properly disposed once the red safety guard is removed [see STORAGE AND HANDLING (16.2)]. Complete patient information, including dosage, directions for proper administration and precautions can be found inside each Auvi-Q™ carton.

INSTRUCTIONS for Use

How to use Auvi-Q™

1. Pull Auvi-Q™ from the outer case

Do not proceed to step 2 until you are ready to use Auvi-Q™. If not ready to use, replace the outer case.

2. Pull off Red safety guard

To avoid an accidental injection, never touch the black base of the auto-injector. If an accidental injection does occur, seek medical help immediately. NOTE: The safety guard is meant to be tight. Pull firmly to remove.

3. Place black end against the middle of the outer thigh (through clothing, if necessary), then press firmly and hold in place for 5 seconds. Each device is a single-use injection. Only inject into the middle of the outer thigh (upper leg). Do not inject into any other location. Note: Auvi-Q™ makes a distinct sound (click and hiss) when activated. This is normal and indicates Auvi-Q™ is working correctly. Do not pull Auvi-Q™ away from your leg when you hear the click and hiss sound.

4. Seek medical attention immediately

Replace the outer case and take your used Auvi-Q™ with you to a healthcare professional for proper disposal and a prescription refill.

AFTER using Auvi-Q™

Seek medical attention immediately.

With a severe, long-lasting allergic reaction, you may need to administer an additional Auvi-Q™. More than two sequential doses of epinephrine should only be administered under direct medical supervision. Following administration of Auvi-Q™:

- The black base will lock into place.
- The voice instruction system will confirm Auvi-Q™ has been used and the LED lights will blink red.
- The red safety guard cannot be replaced.
- The viewing window will no longer be clear.
- Some medicine will remain in Auvi-Q™. However, the injection is complete and you have received the correct dose of the medication.
- Take to your healthcare provider for proper disposal (never discard Auvi-Q™ in regular trash).*
- Discuss your medical history and current medications with the healthcare professional (for example, diabetic patients may need to adjust the dose of their diabetes medicines or insulin after using Auvi-Q™).

Auvi-Q™ and any remaining medicine cannot be reused. Until you dispose of your used Auvi-Q™, the interactive instruction system will remind you that it has been used whenever you remove the outer case.

General information about the safe and effective use of Auvi-Q™

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Auvi-Q™ for a condition for which it was not prescribed.

Never give Auvi-Q™ to other people, even if they have the same symptoms you have.

This leaflet summarizes the most important information about Auvi-Q™. If you would like more information, talk with your Healthcare Provider or Pharmacist.