

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Auvi-Q™ safely and effectively. See full prescribing information for Auvi-Q™.

Auvi-Q™ (epinephrine injection, USP) 0.3 mg, 0.15 mg Auto-Injector

Initial U.S. Approval: 2012

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)

DOSAGE 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)

DOSAGE 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

- 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)
- 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)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-633-1610 or FDA at 1-800-FDA-1088 or 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. (5.4, 8.5)

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

Revised: August 2012

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*Sections or subsections omitted from the full prescribing information are not listed.

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., 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.

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, pruritus, rashes, 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 pounds to 66 pounds): 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.

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 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.
- **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)*].

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.

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.

The alternatives to using epinephrine in a life-threatening situation may not be satisfactory.

5.4 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 Auvi-Q™ 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

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)*].

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs [*see WARNINGS AND PRECAUTIONS (5.4) and DRUG INTERACTIONS (7)*].

Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease [*see WARNINGS AND PRECAUTIONS (5.4)*].

Angina may occur in patients with coronary artery disease [*see WARNINGS AND PRECAUTIONS (5.4)*].

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.

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

Teratogenic Effects: Pregnancy Category C.

There are no adequate and well controlled studies of the acute effect of epinephrine in pregnant women.

Epinephrine was teratogenic in rabbits, mice and hamsters. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (fetal anoxia, spontaneous abortion, or both).

Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal dose of 1.2 $\text{mg}/\text{kg}/\text{day}$ for two to three days), in mice at approximately 7 times the maximum daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 1 $\text{mg}/\text{kg}/\text{day}$ for 10 days), and in hamsters at approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 0.5 $\text{mg}/\text{kg}/\text{day}$ for 4 days).

These effects were not seen in mice at approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a subcutaneous maternal dose of 0.5 $\text{mg}/\text{kg}/\text{day}$ for 10 days).

8.3 NURSING MOTHERS

It is not known whether epinephrine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Auvi-Q™ is administered to a nursing woman.

8.4 PEDIATRIC USE

Auvi-Q™ may be given safely to pediatric patients at a dosage appropriate to body weight [*see DOSAGE AND ADMINISTRATION (2)*]. However, studies in pediatric patients weighing less than 15 kg (33 pounds) have not been conducted.

8.5 GERIATRIC USE

Clinical studies of Auvi-Q™ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Epinephrine 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

Auvi-Q™ (epinephrine injection, USP) 0.3 mg and 0.15 mg is an auto-injector and a combination product containing drug and device components.

Auvi-Q™ includes audible (electronic voice instructions, beeps) and visible (LED lights) cues for use.

Each Auvi-Q™ 0.3 mg delivers a single dose of 0.3 mg epinephrine from epinephrine injection, USP (0.3 mL) in a sterile solution.

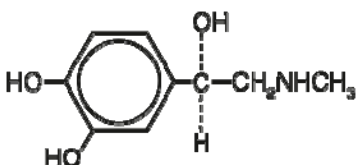
Each Auvi-Q™ 0.15 mg delivers a single dose of 0.15 mg epinephrine from epinephrine injection, USP (0.15 mL) in a sterile solution.

Auvi-Q™ 0.3 mg and Auvi-Q™ 0.15 mg each contain 0.76 mL epinephrine solution. 0.3 mL and 0.15 mL epinephrine solution is dispensed for Auvi-Q™ 0.3 mg and Auvi-Q™ 0.15 mg, respectively, when activated. The remaining solution is not available for future use and should be discarded.

Each 0.3 mL in Auvi-Q™ 0.3 mg contains 0.3 mg epinephrine, 2.3 mg sodium chloride, 0.5 mg sodium bisulfite, hydrochloric acid to adjust pH, and water for injection. The pH range is 2.2–5.0.

Each 0.15 mL in Auvi-Q™ 0.15 mg contains 0.15 mg epinephrine, 1.2 mg sodium chloride, 0.2 mg sodium bisulfite, hydrochloric acid to adjust pH, and water for injection. The pH range is 2.2–5.0.

Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is (-)-3,4-Dihydroxy- α -[(methylamino)methyl]benzyl alcohol with the following structure:



Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

Auvi-Q™ is not made with natural rubber latex.

Auvi-Q™ instructional and safety systems should be thoroughly reviewed with patients and caregivers prior to use [*see PATIENT COUNSELING INFORMATION (17.1)*].

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* 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

16.1 HOW SUPPLIED

Carton containing two Auvi-Q™ (epinephrine injection, USP) 0.3 mg auto-injectors and a single Auvi-Q™ Trainer - NDC 0024-5833-02

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 essential for the 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 allergens, 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 injection. Advise patients to 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)*].

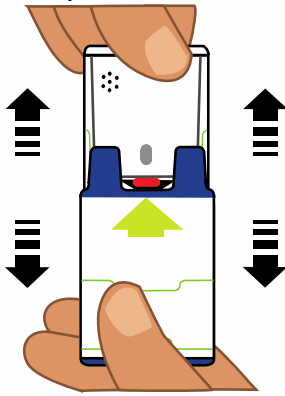
Complete patient information, including dosage, directions for proper administration and precautions can be found inside each Auvi-Q™ carton.

INSTRUCTIONS for Use

How to use Auvi-Q™

1. Pull Auvi-Q™ from the outer case

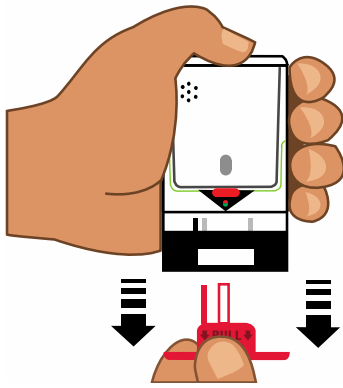
Do **not** proceed to step 2 until you are ready to use Auvi-Q™. If not ready to use, replace the outer case.



2. Pull off **Red** safety guard

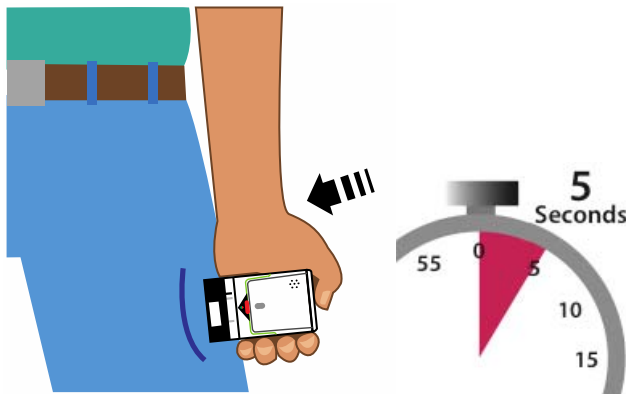
To avoid an accidental injection, **never** touch the black base of the auto-injector. If an accidental injection does occur, seek medical help immediately.

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.

Revised August 2012
Manufactured for:
sanofi-aventis U.S. LLC
Bridgewater, NJ 08807

***For California Only: This product uses batteries containing Perchlorate Material – special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate**

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