PRESCRIBING INFORMATION

ALLERJECT™

Sterile epinephrine injection, USP

Unidose 0.3 mg/0.3 mL epinephrine
Unidose 0.15 mg/0.15 mL epinephrine

Voice-assisted Auto Injector

Pharmaceutical standard: USP

Catecholamine/Sympatomimetic

ATC Code: C01CA24

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Date of Preparation:
May 28, 2013

Submission Control No: 164253

s-a 2.0 Version dated May 28, 2013

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Epinephrine

Route of Administration	**Dosage Form / Strength**	**Nonmedicinal Ingredients**
Intramuscular injection Inject into anterolateral aspect of the thigh. **Do not inject into the buttock.**	Unidose 0.3 mg/0.3 mL epinephrine auto-injector [1:1000]	hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection
	Unidose 0.15 mg /0.15 mL epinephrine auto-injector [1:1000]	

INDICATIONS AND CLINICAL USE

ALLERJECT 0.3 mg (0.3 mL Epinephrine Injection, USP, 1:1000) and ALLERJECT 0.15 mg (0.15 mL Epinephrine Injection, USP, 1:1000) 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).

ALLERJECT is 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.

ALLERJECT is 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. After injection seek immediate medical attention. All individuals receiving emergency epinephrine must be immediately transported to hospital, ideally by ambulance, for evaluation and observation.

Clinical Signs and Symptoms of Anaphylaxis

Anaphylaxis is a serious, acute, allergic reaction that may cause death. 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. 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. 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.

Epinephrine injection 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. More than two sequential doses of epinephrine should only be administered under direct medical supervision (See DOSAGE AND ADMINISTRATION section).

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

Following the resolution of an anaphylactic episode and discharge from hospital, the patient should immediately obtain and fill a new ALLERJECT auto-injector prescription.

Injection site

ALLERJECT **should ONLY be injected into the anterolateral aspect of the thigh** (see DOSAGE AND ADMINISTRATION - Dosing Considerations).

Patients should be advised that ALLERJECT is not intended for intravenous injection. 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.

Patients should be advised that ALLERJECT is not intended for injection into the 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.

Patients should be advised that ALLERJECT is not intended for injection 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. Treatment of such inadvertent administration should consist of vasodilation, in addition to further appropriate treatment of anaphylaxis (see ADVERSE REACTIONS section).

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

Pregnant Women: 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 foetus.

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.

Geriatrics (patients > 65 years of age): Elderly patients with hypertension, coronary artery disease or cardiac arrythmias are particularly at risk for epinephrine overdose. More careful monitoring and avoidance of epinephrine overdose is recommended for these patients.

See DOSAGE AND ADMINISTRATION section for dosage requirements based on weight.

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 section).

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, tripelennamine, 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

A health professional should review the patient instructions and operation of ALLERJECT, in detail, with the patient or caregiver (see CONSUMER INFORMATION section).

Epinephrine is essential for the treatment of anaphylaxis. Patients who are at risk of or with a history of severe allergic reactions (anaphylaxis) should be carefully instructed about the circumstances under which epinephrine should be used (See INDICATIONS AND CLINICAL USE Section).

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 episode, repeat injections of epinephrine may be necessary.

More than two sequential doses of epinephrine should only be administered under direct medical supervision (see WARNINGS AND PRECAUTIONS section).

Voice-assisted auto injector

The voice-assisted auto injector is designed to accurately deliver the required dosage of epinephrine for immediate self-administration for the emergency treatment of severe allergic reactions (Type I), including anaphylaxis (See INDICATIONS AND CLINICAL USE section).

The injector has been designed to be easy-to-use, portable and ergonomic in order to assist patients with complying with recommendations that epinephrine should be available at all times and administered without delay in an allergic emergency. The device also includes several features to mitigate use-related hazards, such as a retractable needle system, a safety tab mechanism, and an electronic voice and visual prompt system that assist the user through the injection process (See DOSAGE FORMS, COMPOSITION AND PACKAGING section).

Dosing Considerations

Selection of the appropriate dosage strength (ALLERJECT 0.3 mg or ALLERJECT 0.15 mg) is determined according to patient body weight. A physician who prescribes ALLERJECT 0.3 mg or ALLERJECT 0.15 mg auto-injector 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.

ALLERJECT 0.3 mg auto-injector contains 0.76 mL of solution but delivers a single dose of 0.3 mL only, with 0.46 mL remaining in the unit, after activation. The remaining volume cannot be used.

ALLERJECT 0.15 mg auto-injector contains 0.76 mL of solution but delivers a single dose of 0.15 mL only, with 0.61 mL remaining in the unit, after activation. The remaining volume cannot be used.

Inject ALLERJECT intramuscularly into the anterolateral aspect of the thigh, through clothing if necessary. **Do not inject into the buttock** (see WARNINGS AND PRECAUTIONS and DOSAGE AND ADMINISTRATION sections).

Recommended Dose and Dosage Adjustment

ALLERJECT 0.3 mg

- ALLERJECT 0.3 mg delivers 0.3 mg epinephrine injection (0.3 mL, 1:1000) and is intended for patients who weigh 30 kg or more.

ALLERJECT 0.15 mg

- ALLERJECT 0.15 mg delivers 0.15 mg epinephrine injection (0.15 mL, 1:1000) and is intended for patients who weigh 15 to 30 kg.

Each ALLERJECT contains a single dose of epinephrine. Since the doses of epinephrine delivered from ALLERJECT are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary.

Administration

ALLERJECT instructional and safety systems should be thoroughly reviewed with patients and caregivers prior to use (see CONSUMER INFORMATION sections).

The epinephrine solution in the viewing window of ALLERJECT should be inspected visually for particulate matter and discoloration (see DOSAGE AND ADMINISTRATION and STORAGE AND STABILITY sections).

Replace ALLERJECT if the epinephrine solution appears cloudy, discolored, contains particles, if the **RED** safety guard has previously been removed, or the expiration date has passed.

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light (see STORAGE AND STORAGE AND STABILITY section).

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

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 alphaadrenergic 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 ALLERJECT auto-injector in the carrier case until use.

Store at room temperature between 15° - 30°C. Do not refrigerate. Protect from light.

Periodically check to make sure the solution in the auto-injector is not brown in color. Replace auto-injector if solution shows haziness, particulate matter, discoloration or leakage.

Replace auto-injector before expiry.

DOSAGE FORMS, COMPOSITION AND PACKAGING

ALLERJECT 0.3 mg or ALLERJECT 0.15 mg auto-injectors are designed to be compact and easy to carry.

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

ALLERJECT 0.3 mg voice-assisted auto-injector

- Each auto-injector contains: 0.76 mL epinephrine injection 1:1000 and is designed to deliver a single dose of epinephrine 0.3 mg in 0.3 mL.

- Approximately 0.46 mL remains in the ALLERJECT 0.3 mg, after activation and cannot be used.

- **Nonmedicinal ingredients:** Each 0.3 mL contains: sodium metabisulfite, sodium chloride, hydrochloric acid to adjust pH and water for injection. Contains no latex.

ALLERJECT 0.15 mg voice-assisted auto-injector

- Each auto-injector contains: 0.76 mL epinephrine injection 1:1000 and is designed to deliver a single dose of epinephrine 0.15 mg in 0.15 mL.

- Approximately 0.61 mL remains in the ALLERJECT 0.15 mg, after activation and cannot be used.

- **Nonmedicinal ingredients:** Each 0.15 mL contains: sodium metabisulfite, sodium chloride, hydrochloric acid to adjust pH and water for injection. Contains no latex.

How supplied

ALLERJECT 0.3 mg voice-assisted auto-injector

- Carton containing one ALLERJECT 0.3 mg (epinephrine injection, USP, 1:1000, 0.3 mL) with English voice-assisted auto-injector.

- Carton containing one ALLERJECT 0.3 mg (epinephrine injection, USP, 1:1000, 0.3 mL) with French voice-assisted auto-injector.

ALLERJECT 0.15 mg voice-assisted auto-injector

- Carton containing one ALLERJECT 0.15 mg (epinephrine injection, USP, 1:1000, 0.15 mL) with English voice-assisted auto-injector.

- Carton containing one ALLERJECT 0.15 mg (epinephrine injection, USP, 1:1000, 0.15 mL) with French voice-assisted auto-injector.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

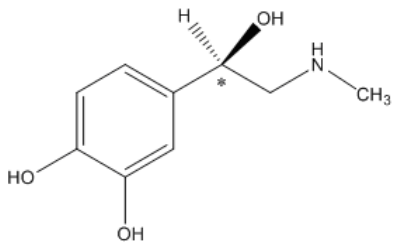
Drug Substance

Proper name: Epinephrine

Chemical name: 1,2-Benzenediol, 4- [1-hydroxy-2-(methylamino)ethyl]-, (R)-. (-)-3,4-Dihydroxy- α-[(methylamino)methyl]benzyl alcohol

Molecular formula and molecular mass: $C_9H_{13}NO_3$, 183.20

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.

TOXICOLOGY

REPRODUCTION

Teratogenic Effects

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/m^2 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/m^2 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/m^2 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/m^2 basis).

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PART III: CONSUMER INFORMATION

ALLERJECT™
Sterile epinephrine injection, USP

Unidose 0.3 mg/0.3 mL epinephrine
Unidose 0.15 mg/0.15 mL epinephrine

Voice-assisted Auto Injector
This leaflet is part III of a three-part "Prescribing Information" published when ALLERJECT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALLERJECT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

You and your caregiver should read this information carefully before using ALLERJECT. You should know how to use ALLERJECT before you have an allergic emergency. ALLERJECT is not a substitute for immediate medical care. After injection seek immediate medical attention. This information contains more details than the quick reference instructions on the ALLERJECT label. This information should not take the place of a careful discussion with your healthcare professional regarding your medical condition or your treatment.

What the medication is used for:

ALLERJECT is indicated for the emergency treatment of serious allergic reactions (anaphylaxis) and is intended for people who are at risk and for people with a history of serious allergic reactions (anaphylaxis).

ALLERJECT 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. After injection, seek immediate medical attention.

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:

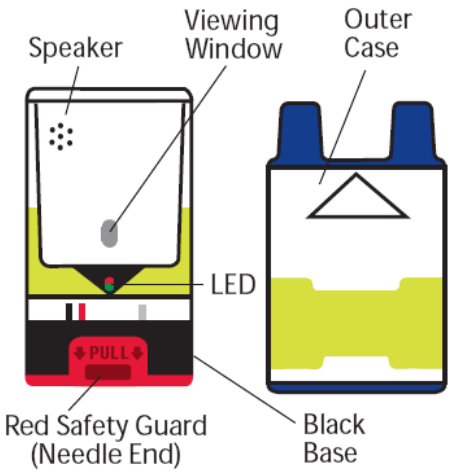
- who have previously experienced allergic reactions or anaphylaxis
- who suffer from asthma
- who have food allergies

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 is ALLERJECT?



ALLERJECT provides an emergency injection of epinephrine by an auto injector device.

IMPORTANT: PLEASE READ

ALLERJECT includes:

- An outer case that protects the epinephrine from sunlight and, when removed, turns on the voice instructions.
- A **RED** safety guard that prevents accidental activation of the injection.
- Visual prompts (Light-emitting diodes or LEDs) and electronic voice instructions to assist in guiding a user through correct administration.
- A retractable needle system that will automatically inject the needle upon activation, deliver epinephrine through the needle, and retract the needle fully into the housing once the injection is complete. A user will not see the needle before, during, or after administration.

What it does:
ALLERJECT contains 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

When it should not be used:
There are no absolute reasons for not using ALLERJECT in a life threatening allergic reaction. However, as discussed below, it is important to tell your doctor or pharmacist about any medical conditions and medications you take prior to using ALLERJECT.

What the medicinal ingredient is:
Epinephrine

What the nonmedicinal ingredients are:
Sodium metabisulfite, sodium chloride, hydrochloric acid and water for injection.

What dosage forms it comes in:

ALLERJECT 0.3 mg
Unidose 0.3 mg epinephrine voice-assisted auto-injector.

ALLERJECT 0.15 mg
Unidose 0.15 mg epinephrine voice-assisted auto-injector.

ALLERJECT 0.3 mg and ALLERJECT 0.15 mg come in disposable, prefilled automatic injection devices.

WARNINGS AND PRECAUTIONS

If you or your child have had one or more episodes of anaphylaxis or if you or your child are determined to be at risk of anaphylaxis, you (or the caregiver) should carry ALLERJECT at all times. You or you child should also wear some form of medical identification bracelet or necklace.

ALLERJECT is not intended as a substitute for medical attention or hospital care. After you use ALLERJECT always seek medical care immediately.

What should you tell your doctor or pharmacist before using ALLERJECT?

BEFORE you obtain ALLERJECT, talk to your doctor or pharmacist about all of your medical conditions, especially if you:

- Have heart disease, irregular heartbeat, or high blood pressure
- Have diabetes
- Have thyroid conditions
- Have narrow-angle glaucoma
- Have depression or other mental disease
- Have Parkinson's disease
- Have Asthma
- Have previously had an allergic reaction
- are pregnant or breast feeding
- any allergies to this drug or its ingredients or components of the container (See "When it should not be used" section)

ALLERJECT remains the essential treatment for anaphylaxis even if you have the above conditions.

Tell your doctor or pharmacist about every medicine you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Some medicines, especially those for asthma, may cause serious side effects if taken while using ALLERJECT**.**

Do not inject ALLERJECT in the vein. Accidental injection of epinephrine in your vein may increase your blood pressure quickly and result in bleeding of the brain (stroke).

IMPORTANT: PLEASE READ

ALLERJECT should NOT be injected into the buttock as the drug may not work properly. If you accidentally inject ALLERJECT into the buttock, go immediately to the nearest emergency room for treatment.

ALLERJECT 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 ALLERJECT into the hands or feet, go immediately to the nearest emergency room for treatment.

For children under 15 kg talk to your doctor about using other forms of injectable epinephrine.

INTERACTIONS WITH THIS MEDICATION

Some medicines may affect how ALLERJECT works, or ALLERJECT may affect how your medicines work.

Medications that may interact with ALLERJECT include:

- Heart rhythm medicines, such as digoxin or quinidine (another name for digoxin is digitalis)
- Diuretic medicines ("water pills")
- MAO inhibitors (MAOI), such as selegilline, isocarboxazid, phenelzine sulfate, or tranylcypromine
- Tricyclic antidepressants, such as amitriptyline, doxepin, nortriptyline
- Antihistamines, such as chlorpheniramine, tripelennamine, or diphenhydramine
- Beta-adrenergic blocking drugs (beta blockers), such as propranolol
- Alpha-adrenergic blocking drugs (alpha blockers), such as phentolamine
- Ergot alkaloids and phenothiazines
- Bronchodilators used for asthma, such as isoproterenol, orciprenaline, salbutamol and long-acting beta agonists (LABAs)
- Thyroid medications (e.g. sodium levothyroxine)
- Cocaine

PROPER USE OF THIS MEDICATION

If you or your child have been told by your doctor that you are at risk for an anaphylactic reaction, you (or the caregiver) should carry ALLERJECT at all times. You or your child should also wear some form of medical identification bracelet or necklace.

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 ALLERJECT. In addition, if you experience any of the symptoms of anaphylaxis listed in the "ABOUT THIS MEDICATION" section, you should administer ALLERJECT 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 ALLERJECT.

Important Information You Need to Know BEFORE using ALLERJECT

How should you be ready for an allergic emergency?

1. **Always carry ALLERJECT** with you because you cannot predict when a life-threatening allergic reaction may occur.
2. **Tell others** where you keep your auto-injector in case you are unable to speak in an allergic emergency.
3. **Examine** the auto-injector often. The medicine in the viewing window of the auto-injector should be clear and colorless. If the medicine looks cloudy, discolored, or contains particles, or the expiration date has passed, ALLERJECT should be replaced.
4. **Always keep ALLERJECT** at room temperature and away from direct light. Direct light and extreme temperatures including excessive heat or cold can damage the medicine.
5. Depending on the severity of reaction, **you may require an additional dose** of epinephrine.

Practice with the Trainer for ALLERJECT First

The Trainer for ALLERJECT does not contain a needle or drug. You should use it to practice before an allergic emergency occurs to support safe and confident use of the actual ALLERJECT auto-injector.

Additional video instructions on the use of ALLERJECT are available at www.allerject.ca.

Usual dose:
Each ALLERJECT contains a single dose of epinephrine and is for single patient use only. Your doctor or your pharmacist will recommend the correct dose for you:

- ALLERJECT 0.3 mg should be used for adults and children weighing 30 kg or more.

- ALLERJECT 0.15 mg should be used for children weighing between 15 kg to 30 kg.

IMPORTANT: PLEASE READ

For children weighing less than 15 kg see WARNINGS AND PRECAUTIONS section.

INSTRUCTIONS for Use

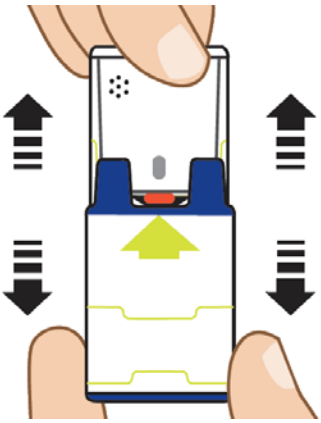
Automated Voice Instructions

ALLERJECT contains an electronic voice instruction system to help guide you through each step of your injection. If the voice instructions do not work for any reason, use ALLERJECT as instructed in these Instructions for Use. It will still work during an allergic reaction emergency.

How to use ALLERJECT

1. Pull ALLERJECT from the outer case

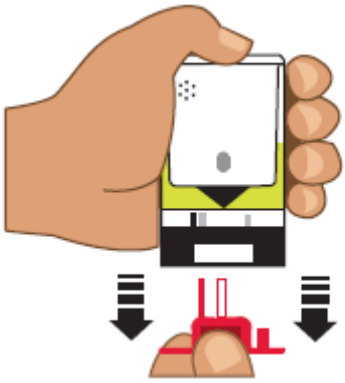
Do not go to step 2 until you are ready to use ALLERJECT. If you are not ready to use, put it back in the outer case.



2. Pull off RED safety guard

To reduce the chance of an accidental injection, do not touch the black base of the auto-injector, which is where the needle comes out. If an accidental injection happens, get medical help immediately.

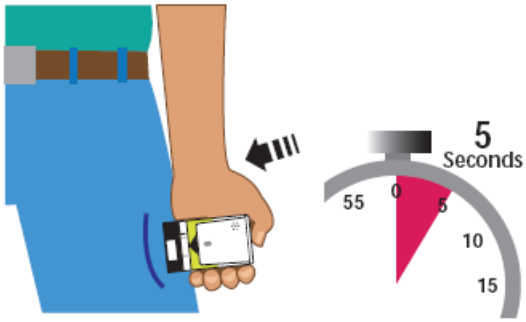
NOTE: The safety guard is meant to be tight. ***Pull firmly to remove.***



3. Place BLACK end AGAINST the MIDDLE of the OUTER thigh (through clothing, if necessary), then press firmly and hold in place for five seconds.

Only inject into the middle of the outer thigh (upper leg). **Do not** inject into any other location.

Note: ALLERJECT makes a distinct sound (click and hiss) when you press it against your leg. This is normal and indicates ALLERJECT is working correctly.



4. Seek immediate medical or hospital care.

Replace the outer case and take your used ALLERJECT with you to your pharmacist or physician for proper disposal and replacement.

AFTER using ALLERJECT
Seek immediate Medical Attention

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

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 ALLERJECT.

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.

Following administration ALLERJECT:

- The black base will lock into place.
- The voice instruction system will say ALLERJECT has been used and the lights will blink red.
- The **RED** safety guard cannot be replaced.
- The viewing window will no longer be clear.
- Some medicine will remain in ALLERJECT. However, the injection is complete and you have received the correct dose of the medication.
- Take to your doctor or pharmacist for proper disposal (never discard ALLERJECT 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 ALLERJECT).

Request a prescription refill or a replacement

ALLERJECT and any remaining medicine cannot be reused. You will now need a prescription refill or a replacement for a new ALLERJECT. Until you dispose of your used ALLERJECT, the electronic voice instruction system will remind you that it has been used when you remove the outer case.

General information about the safe and effective use of ALLERJECT

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not ALLERJECT for a condition for which it was not prescribed.

Never give ALLERJECT to other people, even if they have the same symptoms you have.

This leaflet summarizes the most important information about ALLERJECT.

If you would like more information, talk with your doctor or pharmacist.

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

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

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ALLERJECT is 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 ALLERJECT, always seek appropriate medical care. ALLERJECT does not replace seeing a doctor or going to the hospital.

Patients with certain medical conditions, or who take certain medications, may get more or longer lasting side effects with ALLERJECT. This includes patients who take certain types of medicines for asthma, allergies, depression, hyperthyroidism, high blood pressure, and heart disease.

Patients with heart disease may feel chest pain (angina).

Patients with mental disease or Parkinson's disease may have worsening symptoms of their illness.

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

Other potential side effects include:

- Paleness
- Shaking
- Throbbing
- Restlessness
- Anxiety
- Tenseness
- Fear

IMPORTANT: PLEASE READ

ALLERJECT (epinephrine) can also cause the following serious side effects. Most of them usually decrease with rest.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM		
		Seek Medical Attention
		In all cases
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)	√

This is not a complete list of side effects. For any unexpected effects while taking ALLERJECT, contact your doctor or pharmacist.

It is important that you seek immediate medical assistance or go to the emergency room immediately after using ALLERJECT.

HOW TO STORE IT

- Keep your ALLERJECT at room temperature. Do not refrigerate. Do not drop.
- Do not expose your ALLERJECT to direct sunlight.
- Do not keep your ALLERJECT in a vehicle during extremely hot or cold weather.
- Always keep your ALLERJECT in the carrier case until you need to use it.
- Occasionally inspect your ALLERJECT solution through the viewing window. Replace your ALLERJECT if it is discolored or contains solid particles (precipitate) or if there are any signs of leakage. The solution should be clear.
- Replace if there are any signs of damage to the carrier or the ALLERJECT.
- Do not attempt to tamper with or dismantle ALLERJECT 0.3 mg or ALLERJECT 0.15 mg.
- Replace your ALLERJECT before the expiration date or after you use it.
- Talk to your pharmacist or physician about how to properly dispose of your expired ALLERJECT.
- Do not place this Consumer Information or any other objects in the carrier case with your ALLERJECT, as this may prevent you from removing your ALLERJECT quickly for use.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Prescribing Information, prepared for health professionals can be found at: http://www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1855-GØ-54321 (1-855-405-4321).

Register your ALLERJECT lot number at www.allerject.ca for product expiry reminder.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: May 28, 2013