

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

ALLERJECT® 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 release of chemicals that can lead to life-threatening symptoms.

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

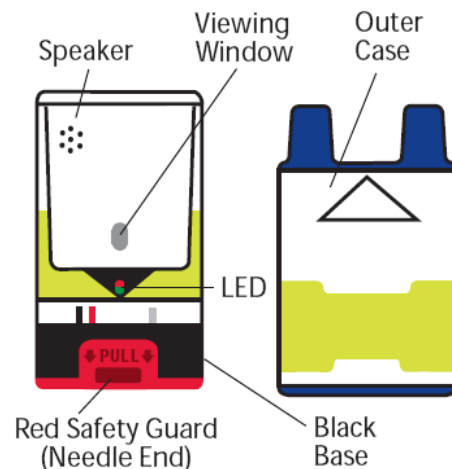
- who have previously experienced allergic reactions or anaphylaxis
- who suffer from asthma
- who have food allergies

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.

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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 your 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
- Have 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).

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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.

If you inject a young child with ALLERJECT hold their leg firmly in place and limit movement before and during the injection to prevent injuries. Ask your healthcare provider to show you how to properly hold the leg of a young child during an injection.

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 selegiline, isocarboxazid, phenelzine sulfate, or tranylcypromine
- Tricyclic antidepressants, such as amitriptyline, doxepin, nortriptyline
- Antihistamines, such as chlorpheniramine, triproleamine, 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:

IMPORTANT: PLEASE READ

- 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.

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

INSTRUCTIONS for Use

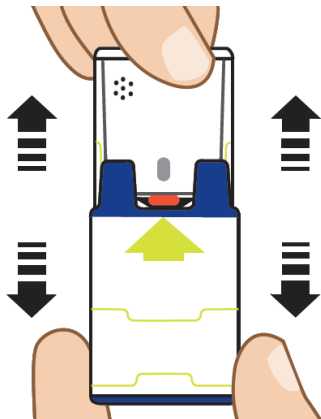
Automated Voice Instructions

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

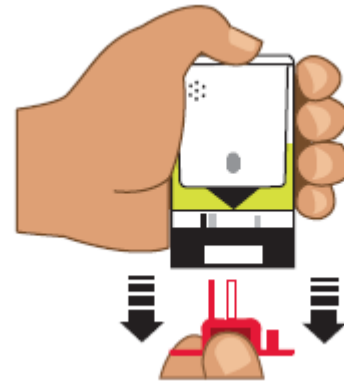
Do not go to step 2 until you are ready to use ALLERJECT. If you are not ready to use, put it back in the outer case.



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.***

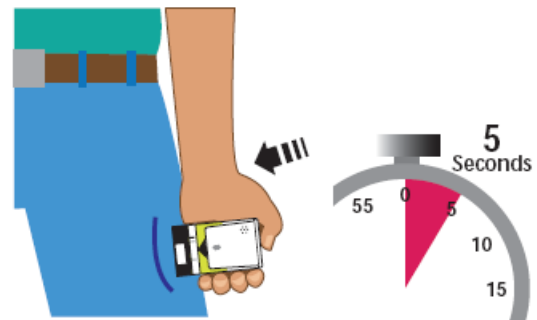


3. Place **BLACK** end **AGAINST** the **MIDDLE** of the **OUTER thigh** (through clothing, if necessary), then **press firmly and hold in place for five seconds.**

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

If you are administering ALLERJECT to a young child, hold the leg firmly in place while administering the injection.

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.

IMPORTANT: PLEASE READ

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 of 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 use 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

Rarely, patients who use ALLERJECT may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following at an injection site:

- Redness that does not go away
- Swelling
- Tenderness
- The area feels warm to the touch

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 SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at **1-866-234-2345**

NOTE: Contact your health professional if you need information about how to manage your side effects. 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.allerject.ca> or by contacting the sponsor, kaleo, Inc. USA, at: **1-888-680-7340**.

This leaflet was prepared by kaleo, Inc. USA.

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