

PART III: CONSUMER INFORMATION

EpiPen®
Sterile epinephrine injection, USP
Unidose 0.3 mg epinephrine Auto-injector

EpiPen Jr®
Sterile epinephrine injection, USP
Unidose 0.15 mg epinephrine Auto-injector

This leaflet is Part III of a three-part “Prescribing Information” document published when EpiPen®, EpiPen Jr® were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EpiPen®, EpiPen Jr®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

EpiPen® and EpiPen Jr® are indicated for the emergency treatment of anaphylaxis and are intended for people determined to be at risk for serious allergic reactions and for people with a history of anaphylactic reactions.

EpiPen® and EpiPen Jr® 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.

Anaphylaxis is the term for a severe, life-threatening allergic reaction. 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.

Some common allergens include:

- foods like peanuts, tree nuts, shellfish, fish, milk, eggs and wheat
- insect stings like those from bees, wasps, hornets, yellow jackets and fire ants
- insect bites like those from mosquitos and black flies
- certain medicines
- latex
- other allergens (a substance that causes allergies)

These severe allergic reactions can also be caused by exercise, asthma or by unknown causes.

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
- Hives
- Difficulty breathing or swallowing
- Wheezing and cough
- Metallic taste or itching in the mouth
- Flushing, itching, or redness of the skin
- Stomach cramps, nausea, vomiting, or diarrhea
- Increased heart rate
- Decreased blood pressure
- Chest pain
- Irregular heart beat
- Paleness
- Sudden feeling of weakness
- Feeling faint
- Anxiety or an overwhelming sense of doom
- Collapse
- Loss of consciousness

What it does:

EpiPen® and EpiPen Jr® contain 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

What the medicinal ingredient is:

Epinephrine.

What the nonmedicinal ingredients are:

Hydrochloric acid, sodium chloride, sodium metabisulfite, and water for injection.

What dosage forms it comes in:

EpiPen®: Unidose 0.3 mg epinephrine auto-injector

EpiPen Jr®: Unidose 0.15 mg epinephrine auto-injector

EpiPen® and EpiPen Jr® come in disposable, prefilled automatic injection devices.

EpiPen® and EpiPen Jr® are single-use injectable devices that deliver a fixed dose of epinephrine.

WARNINGS AND PRECAUTIONS

BEFORE you obtain EpiPen® or EpiPen Jr®, talk to your doctor or pharmacist about all of your medical conditions, especially if you have:

- heart disease
- irregular heartbeat
- high blood pressure
- diabetes
- thyroid conditions
- narrow-angle glaucoma
- depression or other mental disease
- Parkinson's disease
- severe kidney disease
- a tumor on the adrenal gland
- a tumor in the prostate gland
- very high calcium levels in your blood
- very low potassium levels in your blood
- asthma
- previously had an allergic reaction
- an allergy to any of the ingredients in this medication
- also notify your doctor and pharmacist if you are pregnant or breast feeding

EpiPen® or EpiPen Jr® is the first line emergency treatment for severe, life-threatening allergic reactions even if you have the above conditions.

Other warnings you should know about:

General: If have you had a severe, life-threatening allergic reaction in the past, you are at a higher risk for having one again. You should carry EpiPen® or EpiPen Jr® with you at all times. You or your child should also wear some form of medical identification bracelet or necklace.

Using EpiPen® or EpiPen Jr® does not replace seeing a doctor or going to the hospital. You **must** get medical help **right away** after you or your child has used it.

Patients with Asthma: if you or your child has asthma, and it is not controlled properly, you are at a higher risk of having breathing problems when you have a severe allergic reaction.

EpiPen® or EpiPen Jr® contains metabisulfite. This can cause allergic reactions and bronchospasms in those with a history of asthma. You should follow your doctor's instructions carefully on when you or child can use EpiPen® or EpiPen Jr®.

Injection site: You should **ONLY** inject EpiPen® or EpiPen Jr® into the **outer side of your upper thigh - into the muscle** (see Proper Use of this Medication).

Do not inject it into the:

- vein (intravenously (IV))
- buttocks
- hands, fingers, feet and toes

If you do, it can either cause dangerously high blood pressure or you or your child may not get the effect of the emergency treatment that you or they need.

If you accidentally inject it into any of these areas, **go right away** to the nearest hospital (emergency room) for further treatment.

If you inject a young child with EpiPen® or EpiPen Jr® 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 injection.

If you have a thick layer of fat under your skin the epinephrine in EpiPen® or EpiPen Jr® may not reach your muscle tissue. In some cases this might make EpiPen® and EpiPen Jr® not work as well.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with EpiPen® or EpiPen Jr® include:

- Heart rhythm medicine, 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 tranlycypromine
- Tricyclic antidepressants, such as amitriptyline, doxepin, nortriptyline
- Antihistamines, such as chlorpheniramine, tripelemnamine, or diphenhydramine
- Beta-adrenergic blocking drugs, such as propranolol
- Alpha-adrenergic blocking drugs, such as phentolamine
- Ergot alkaloids and phenothiazines
- Isoproterenol, orciprenaline, salbutamol and LABAs
- Thyroid medications (e.g. sodium levothyroxine)
- Cocaine

PROPER USE OF THIS MEDICATION

If you have been told by your doctor that you are at risk for an anaphylactic reaction, carry your EpiPen® or EpiPen Jr® with you at all times.

When your doctor prescribes EpiPen® or EpiPen Jr®, you must make sure you understand the reason it has been prescribed for you. You should be confident that you know exactly how and when to use it.

Use EpiPen® or EpiPen Jr® exactly how your doctor or pharmacist has told you. Ask to have the instructions repeated to you if you are unsure about how to use it. It is recommended that your family members, carers or teachers are also instructed in the correct use of EpiPen® or EpiPen Jr®.

There is a training device (Trainer) which you can use to practice. If you have been stung by an insect, try to remove the stinger with your fingernails. Do not squeeze, pinch or push the stinger deeper into the skin.

If possible, put an ice pack on the area of the sting. Keep yourself warm and avoid exercise.

For allergic reactions caused by foods make sure you remove any remaining food from the mouth immediately.

IMPORTANT NOTE:

Severe, life-threatening allergic reactions (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 EpiPen[®] or EpiPen Jr[®].

Inject EpiPen[®] or EpiPen Jr[®] **right away** if you experience any of the symptoms of a severe allergic reaction, such as swelling of the throat, lips, tongue or around the eyes, trouble breathing or swallowing. You **must** get medical help **right away** after using EpiPen[®] or EpiPen Jr[®]. You can:

- call 911 and get taken to the hospital OR
- you can have someone take you (or you can take your child) to the nearest hospital emergency room

If you or your child do not feel better or get worse you can inject another dose of EpiPen[®] or EpiPen Jr[®] 5 to 15 minutes after the first injection.

Do not inject more than 2 injections right after each other.

Usual dose:

EpiPen[®] (0.3 mg) should be used for adults and children weighing 30 kg or more.

EpiPen Jr[®] (0.15 mg) should be used for children weighing between 15 kg to 30 kg. For children weighing less than 15 kg, call 911.

Directions for Use

Caution

- Remove EpiPen[®] or EpiPen Jr[®] from carrier tube before use
- Never put thumb, fingers or hand over orange tip
- Never press or push orange tip with thumb, fingers, or hand
- The injection needle comes out of orange tip
- Do not remove blue safety release cap until ready to use
- Remove blue safety release cap by pulling straight up (Do not bend or twist off the blue safety release cap)

To Take EpiPen[®] or EpiPen Jr[®] out of the Carrier Tube

1. Flip open the cap on the carrier tube. The cap is yellow on EpiPen[®], green on EpiPen Jr[®].

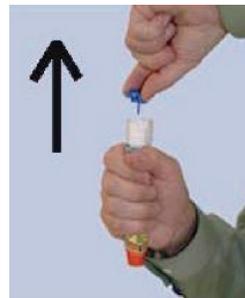


2. Tip the carrier tube and slide EpiPen[®] or EpiPen Jr[®] out of the tube.

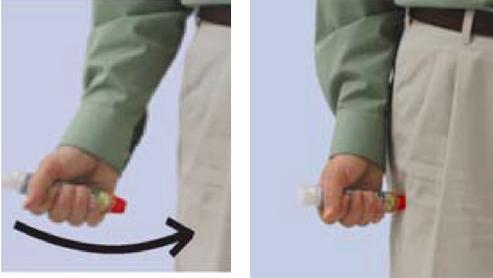


To Use EpiPen[®] or EpiPen Jr[®]

1. Grasp EpiPen[®] or EpiPen Jr[®] with the orange tip pointing downward, form a fist around the unit [orange tip (needle end) down], remove blue safety release cap by pulling straight up. (Do not bend or twist off the blue safety release cap.)



- Place the orange tip against the middle of the outer thigh (upper leg) at a right angle to the thigh. Swing and push the auto-injector firmly until it “clicks”. The click signals that the injection has started. Hold firmly in place for 3 seconds (count slowly, ‘1, 2, 3’). Inject even through clothing if necessary. Do not inject EpiPen® or EpiPen Jr® into your hands, feet, or buttock.



- Remove EpiPen® or EpiPen Jr® from the thigh. Massage the injected area if desired. **Note:** The orange needle cover automatically extends to cover the injection needle when EpiPen® or EpiPen Jr® is removed from the thigh. If the needle is still visible, do not attempt to reuse it.



- The injection is now complete.
- If you are administering EpiPen® or EpiPen Jr® to a young child, hold the leg firmly in place while administering the injection.
- 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 EpiPen® or EpiPen Jr®.**
- 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.**

The used EpiPen® or EpiPen Jr® with extended orange needle cover will not fit back into the carrier. Give any used EpiPen® or EpiPen Jr® to emergency responders or emergency room personnel.

Do not attempt to reuse EpiPen® after the device has been activated.

Overdose:

If you take more than the recommended dose, or inject the EpiPen® or EpiPen Jr® anywhere other than your thigh, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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

Signs of an overdose include:

- irregular heart beat
- difficulty breathing caused by a build-up of fluid in your lungs

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

EpiPen® and EpiPen Jr® are 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 EpiPen® or EpiPen Jr® always seek appropriate medical care. EpiPen® or EpiPen Jr® does not replace seeing a doctor or going to the hospital.

The following side effects may occur after using EpiPen® or EpiPen Jr®.

- Paleness
- Dizziness
- Weakness
- Shaking
- Headache
- Throbbing
- Restlessness
- Anxiety
- Tenseness
- Fear

Patients who have used EpiPen® or EpiPen Jr® 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

Cuts on the skin, bent needles, and needles that remain in the skin after the injection, have happened in young children who do not cooperate and kick or move during an injection.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Difficulty breathing			✓
Increased heart rate (pounding heart)			✓
Irregular or skipped heart beats			✓
Chest pain (angina)			✓
Stroke (blurred vision, difficulty speaking, headache, dizziness and weakness)			✓

This is not a complete list of side effects. For any unexpected effects while taking EpiPen® or EpiPen Jr®, talk to your doctor or pharmacist.

It is important that you seek medical assistance or go to the emergency room immediately after using EpiPen® or EpiPen Jr®.

HOW TO STORE IT

- Keep your EpiPen® or EpiPen Jr® at room temperature. Do not refrigerate. Do not drop.
- Do not expose your EpiPen® or EpiPen Jr® to direct sunlight.
- Do not keep your EpiPen® or EpiPen Jr® in a vehicle during extremely hot or cold weather.
- Always keep your EpiPen® or EpiPen Jr® in the carrier tube to protect it from damage; however, the carrier tube is not waterproof.
- The blue safety release cap helps to prevent accidental injection. Keep the blue safety release cap on until you need to use EpiPen® or EpiPen Jr®.
- Occasionally inspect your EpiPen® or EpiPen Jr® solution through the viewing window. Replace your EpiPen® or EpiPen Jr® if it is discolored or contains solid particles (precipitate) or if there are any signs of leakage. The solution should be clear.
- Discard if there are any signs of damage to the carrier or the EpiPen® or EpiPen Jr®.

- Do not attempt to take the EpiPen® or EpiPen Jr® apart. Replace your EpiPen® or EpiPen Jr® before the expiration date or after you use it.
- Talk to your pharmacist or physician about how to properly dispose of your expired EpiPen® or EpiPen Jr®.
- Do not place this Consumer Information or any other objects in the carrier tube with your EpiPen® or EpiPen Jr®, as this may prevent you from removing your EpiPen® or EpiPen Jr® quickly for use.
- Keep out of the reach and sight of children.

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.

EXPIRATION REMINDER SERVICE

Patients may also register the expiration date of their EpiPen®, EpiPen Jr® at www.EpiPen.ca. Shortly before this emergency care product expires patients will be notified by E-mail or text message that the product is nearing expiry and should be replaced.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.EpiPen.ca or by contacting Pfizer Canada Inc. 1-877-EPIPEN 1 (1-877-374-7361).

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