

**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 severe allergic reactions (anaphylaxis). They are intended for immediate use in patients who are at increased risk for anaphylaxis, including individuals with a history of having 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 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 tranylcypromine
- Tricyclic antidepressants, such as amitriptyline, doxepin, nortriptyline
- Antihistamines, such as chlorpheniramine, tripelemamine, 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
- Theophylline, used to treat types of lung diseases
- Oxytocin, used during labour
- Parasympatholytic medications, used to reduce activity of the nervous system
- Levodopa, used in the treatment of Parkinson's disease
- Alcohol

## 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 needle end
- Never press or push orange needle end with thumb, fingers, or hand
- The injection needle comes out of orange needle end
- Do not remove blue safety top until ready to use
- Remove blue safety top by pulling straight up (Do not bend or twist off the blue safety top)

**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.

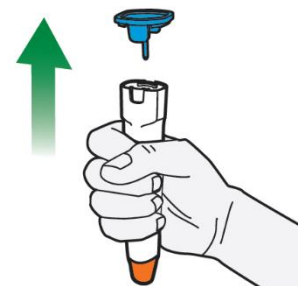


2. Tip the carrier tube and slide EpiPen or EpiPen Jr out of the tube.



**To Use EpiPen or EpiPen Jr**

1. Grasp EpiPen or EpiPen Jr with the orange needle end pointing downward, form a fist around the unit [orange needle end down], pull off blue safety top. (Do not bend or twist off the blue safety top.)



2. Place the orange needle end against the middle of the outer thigh (upper leg) at a right angle to the thigh. Push hard against leg. The pop signals that the injection has started. After pop, 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.



3. 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.



4. The injection is now complete.
5. If you are administering EpiPen or EpiPen Jr to a young child, hold the leg firmly in place while administering the injection.
6. Seek emergency 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. 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.
7. **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 a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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
- Feeling cold

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 20°C – 25°C, excursions permitted to 15°C – 30°C. Do not refrigerate or freeze. Do not drop.
- Do not expose your EpiPen or EpiPen Jr to direct sunlight. Keep out of reach and sight of children.
- 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 top helps to prevent accidental injection. Keep the blue safety top on until you need to use EpiPen or EpiPen Jr.
- Occasionally inspect your EpiPen or EpiPen Jr medicine 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 medicine 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 ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) 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](http://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](http://www.EpiPen.ca) or by contacting BGP Pharma ULC 1-877-EPIPEN 1 (1-877-374-7361).

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