

PATIENT INFORMATION

SYMJEPI™ (sim-JEP-ee)

(epinephrine)

injection, for intramuscular or subcutaneous use

For allergic emergencies (anaphylaxis)

Read this Patient Information leaflet carefully before using SYMJEPI and each time you get a refill. There may be new information. You, your parent, caregiver, or others who may be in a position to administer SYMJEPI should know how to use it before you have an allergic emergency. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about SYMJEPI?

- SYMJEPI contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life threatening, can happen within minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or unknown causes.
Symptoms of anaphylaxis may include:
 - trouble breathing
 - wheezing
 - hoarseness (changes in the way your voice sounds)
 - hives (raised reddened rash that may itch)
 - severe itching
 - swelling of your face, lips, mouth, or tongue
 - skin rash, redness, or swelling
 - fast heartbeat
 - weak pulse
 - feeling very anxious
 - confusion
 - stomach pain
 - losing control of urine or bowel movements (incontinence)
 - diarrhea or stomach cramps
 - dizziness, fainting, or "passing out" (unconsciousness)
- Always carry your SYMJEPI with you because you may not know when anaphylaxis may happen.**
Talk to your healthcare provider if you need additional prefilled syringes to keep at work, school, or other locations. Tell your family members, caregivers, and others where you keep your SYMJEPI and how to use it before you need it. You may be unable to speak in an allergic emergency.
- When you have an allergic emergency (anaphylaxis)**
 - Use SYMJEPI right away.**
 - Get emergency medical help right away.** You may need further medical attention. You may need to use a second SYMJEPI if symptoms continue or recur. Only a healthcare provider should give additional doses of epinephrine if you need more than 2 injections for a single anaphylaxis episode.

What is SYMJEPI?

- SYMJEPI is a disposable, prefilled syringe used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. Each prefilled syringe contains a single (1 time) dose of epinephrine.
- SYMJEPI is for immediate self (or caregiver) administration and does not take the place of emergency medical care. You should get emergency help right away after using SYMJEPI.
- SYMJEPI is for people who have been prescribed this medicine by their healthcare provider.
- The SYMJEPI 0.3 mg prefilled syringe is for patients who weigh 66 pounds or more (30 kilograms or more).
- The SYMJEPI 0.15 mg prefilled syringe is for patients who weigh between 33 and 66 pounds (15 to 30 kilograms).
- It is not known if the SYMJEPI prefilled syringe is safe and effective in patients who weigh less than 33 pounds (15 kilograms).

Before using SYMJEPI, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems or high blood pressure.
- have diabetes.
- have thyroid problems.
- have asthma.
- have a history of depression.
- have Parkinson's disease.
- are pregnant or plan to become pregnant. It is not known if epinephrine will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if epinephrine passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider of all known allergies.

Especially tell your healthcare provider if you take certain asthma medicines.

SYMJEPI and other medicines may affect each other, causing side effects. SYMJEPI may affect the way other medicines work, and other medicines may affect how SYMJEPI works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Use your SYMJEPI for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of your medical conditions or the medicines you take.

How should I use SYMJJEPI?

- Each SYMJJEPI prefilled syringe contains only 1 dose of medicine.
- SYMJJEPI should be injected into the middle of your outer thigh (upper leg) with the needle facing downwards. It can be injected through your clothing if needed.
- Read the Instructions for Use at the end of this Patient Information leaflet about the right way to use SYMJJEPI.
- Your healthcare provider will show you how to safely use the SYMJJEPI prefilled syringe.
- Use SYMJJEPI exactly as your healthcare provider tells you to use it.
- If you inject a young child with SYMJJEPI, hold their leg firmly in place 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.
- You may need to use a second SYMJJEPI if symptoms continue or recur. Only a healthcare provider should give additional doses of epinephrine if you need more than 2 injections for a single anaphylaxis episode.
- **Caution: Never put your thumb, fingers, or hand over the exposed needle.** Accidental injection of epinephrine into the finger, hands or feet may cause a loss of blood flow to these areas. **If this happens, go immediately to the nearest emergency room.** Tell the healthcare provider where on your body you received the accidental injection.
- Always carry your SYMJJEPI with you in case of an allergic emergency. Additional instructional materials and information are available at www.symjjeppi.com.
- Do not drop the carrier case or SYMJJEPI prefilled syringe. If the carrier case or prefilled syringe is dropped, check for damage and leakage. Dispose of the prefilled syringe and carrier case, and replace if damage or leakage is noticed or suspected.

What are the possible side effects of SYMJJEPI?

SYMJJEPI may cause serious side effects.

- **SYMJJEPI should only be injected into the middle of your outer thigh (upper leg). Do not** inject SYMJJEPI into your:
 - veins
 - buttocks
 - fingers, toes, hands or feetIf you accidentally inject SYMJJEPI into any other part of your body, go to the nearest emergency room right away. Tell the healthcare provider where on your body you received the accidental injection.
- **Rarely, patients who have used SYMJJEPI 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. If you inject a young child with SYMJJEPI, hold their leg firmly in place 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 certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use your SYMJJEPI.** Talk to your healthcare provider about all your medical conditions.

Common side effects of SYMJJEPI include:

- fast, irregular or “pounding” heartbeat
- sweating
- headache
- weakness
- shakiness
- paleness
- feelings of over excitement, nervousness or anxiety
- dizziness
- nausea and vomiting
- breathing problems

These side effects may go away with rest. **Tell your healthcare provider if you have any side effect that bothers you or that does not go away.**

These are not all the possible side effects of SYMJJEPI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

How should I store SYMJJEPI?

- Store SYMJJEPI at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.
- **Do not** expose to extreme cold or heat. For example, **do not** store in your vehicle’s glove box and **do not** store in the refrigerator or freezer.
- Examine the contents in the clear window of your prefilled syringe periodically. The solution should be clear. If the solution is discolored (pinkish or brown color), is cloudy, or contains solid particles, replace the unit.
- Always keep your SYMJJEPI prefilled syringe in the carrier case to protect it from damage. **The carrier case is not waterproof.**
- The needle cap helps to prevent accidental injection. Do not remove the needle cap until you need to use SYMJJEPI.
- Your SYMJJEPI has an expiration date. Replace it before the expiration date.

Keep SYMJJEPI and all medicines out of the reach of children.

General information about the safe and effective use of SYMJEPI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SYMJEPI for a condition for which it was not prescribed. Do not give your SYMJEPI to other people.

This Patient Information leaflet summarizes the most important information about SYMJEPI. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about SYMJEPI that is written for health professionals.

What are the ingredients in SYMJEPI?

Active Ingredients: epinephrine

Inactive Ingredients: sodium chloride, sodium metabisulfite, hydrochloric acid, and water.

Manufactured for Adamis Pharmaceuticals Corporation. San Diego, CA

SYMJEPI is a registered trademark of Adamis Pharmaceuticals Corporation.

For more information and instructions on the use of SYMJEPI, go to www.symjepi.com or call 1-858-997-2400.

Important Information

- **Your prefilled syringe is designed to work through clothing.**
- **The needle cap on the SYMJEPI prefilled syringe helps to prevent needle sticks and accidental injection of epinephrine. Do not remove the needle cap until you are ready to use it.**
- **Only inject into the middle of the outer thigh (upper leg). Never inject into any other part of the body.**
- **Never put your thumb, fingers, or your hand over the exposed needle.**
- **If an accidental injection happens, get medical help right away.**
- **Do not place patient information or any other foreign objects in the carrier case with the prefilled syringe, as this may prevent you from removing the prefilled syringe for use.**

This Patient Information has been approved by the U.S. Food and Drug Administration

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