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Kentucky Department for Public Health (KDPH)
CLINICAL PROTOCOL FOR EPINEPHRINE AUTO-INJECTOR USE IN THE SCHOOL SETTING

Background

KRS 158.836 makes provisions for students with life-threatening allergies to have access to an injectable epinephrine device in school, and KRS 158.832 clarifies definitions.

KRS 158.836 includes:

- A student who has a documented life-threatening allergy shall have:
  - An injectable epinephrine device provided by his or her parent or guardian in his or her possession or in the possession of the school nurse, school administrator, or his or her designee in all school environments that the student may be in, including the classroom, the cafeteria, the school bus, and on field trips.
  - A written individual health care plan in place for the prevention and proactive management for the student in all school environments that the student may be in, including the classroom, the cafeteria, the school bus, and on field trips. The individual health care plan may be incorporated in the student's individualized education program or student's 504 plan.
- Each school is encouraged to keep an injectable epinephrine device in a minimum of two (2) locations in the school, including but not limited to the school office and the school cafeteria, so that epinephrine may be administered to any student believed to be having a life-threatening anaphylactic reaction.
- Schools electing to keep injectable epinephrine devices shall maintain them in a secure, accessible, but unlocked location. This shall apply to the extent that the injectable epinephrine devices are donated to a school, or a school has sufficient funding to purchase the injectable epinephrine devices.
- Each school electing to keep injectable epinephrine devices shall implement policies and procedures for managing student's life-threatening allergic reaction or anaphylactic reaction, or asthma developed and approved by the local school board.
- KDPH shall develop clinical protocols in the school health section of the Clinical Service Guide manual to address injectable epinephrine devices and to advise on clinical administration of injectable epinephrine devices.
- Any school employee authorized under KRS 156.502 to administer medication shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the administration or the assistance in the administration of epinephrine to any student believed in good faith to be having a life-threatening allergic or anaphylactic reaction or asthma symptoms or respiratory distress.
  - Any school employee authorized to administer medications should be aware of and understand their protections and liabilities as established in applicable regulations, including KRS 158.836 and KRS 156.502.
- Per KRS 311.646 the KDPH, the Kentucky Board of Medical Licensure, the Kentucky Board of Nursing, the American Red Cross, or other training programs approved by the Department for Public Health may conduct in-person or on-line training for administering lifesaving treatment to persons believed in good faith to be experiencing severe allergic reactions and asthma symptoms or respiratory distress and issue a certificate of training to persons completing the training. The training shall include instructions for recognizing the symptoms of anaphylaxis and asthma and administering an injectable epinephrine device or a bronchodilator rescue inhaler.
- Per KRS 311.646 any individual or entity who acquires and stocks a supply of injectable epinephrine devices in accordance with this section shall notify an agent of the local emergency medical services system and the local emergency communications or vehicle dispatch center of the existence, location, and type of the injectable epinephrine devices acquired if a severe allergic reaction has occurred.

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What is Anaphylaxis?

Anaphylaxis occurs when symptoms affect two or more body systems. It is caused by your immune system flooding your body with chemicals to fight off an allergen. These chemicals often work fast to trigger a cascade of allergy symptoms.

Anaphylaxis is a severe allergic reaction that can progress into a life-threatening condition and can cause death in less than 15 minutes. It is caused by exposure to something the person is allergic to. Symptoms involve multiple body systems including the skin, heart, stomach, and airways. The most common triggers are certain foods, certain medications, and insect stings.

Anaphylaxis is defined in three different ways:

1. Sudden onset of skin symptoms along with respiratory OR circulatory symptoms.
2. Sudden onset of a combination of two body system symptoms.
3. Exposure to allergens and a drop in blood pressure.

What are the most common triggers for anaphylaxis?

- Legumes (such as peanut)
- Animal proteins (such as cow's milk, egg, finned fish, and shellfish)
- Venom from stinging insects (such as bee stings, wasps, and yellow jackets)
- Venom from insect bites (such as fire ants)
- Pain medications (such as aspirin or ibuprofen)
- Tree nuts (such as almonds, walnuts, pecans, and hazelnut), soy, wheat and sesame are other common triggers. Food allergy research reveals more than 170 different foods can trigger allergic reactions.

What are anaphylaxis symptoms?

Symptoms can be different each time a person experiences an anaphylactic reaction. They may vary in severity each time. Once symptoms start, they usually progress quickly.

Signs and Symptoms of the Skin

- Swelling of the face, lips, tongue, neck, and/or hands.
    - Eyes can begin to look puffy and talking and annunciating may become difficult if the lips or tongue swell.
    - Hives are raised, red, and itchy bumps on the skin. The redness of hives is easier to see on lighter skin, but the raised bumps can be felt on anyone.

While skin symptoms such as an itchy rash or hives are common, they do not always occur. Ten to 20 percent of the time, symptoms will occur with no skin symptoms.

Signs and Symptoms of the Respiratory System

- Nasal congestion - stuffy and/or runny nose.
- Wheezing - can sound like a flute when breathing out!
- Coughing.
- Rapid, noisy, and/or difficulty breathing. Someone will struggle to take normal or deep breaths.
- Sudden change or loss of one's voice.
- Trouble swallowing.
    - A child may think they have a sore throat.
- Stridor.
    - High-pitched noise when breathing in.
    - Like a squeaking noise - at times it can sound like a seal-like bark.

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Signs and Symptoms of the Neurological System

- Agitation.
  - Acting strangely & differently than normal.
- Confusion.
  - Confusion can also show up in a child getting quiet when they normally do not. Agitation can be a child getting frustrated or mad at activities that don't normally cause that reaction. Behavioral changes are a sign that not enough oxygen is getting to the brain!
- Headache.
- Fainting & Loss of Consciousness (passing out).
  - This can be a child collapsing and quickly becoming responsive and awake again to collapsing and not reacting to attempts to wake them up.

Signs and Symptoms of the Gastrointestinal System

- Nausea.
  - Can be described as a tummy ache in younger children.
- Vomiting (throwing up).
- Diarrhea (runny stools/poop).
- Stomach pain.
  - May be described as a tummy ache or a child may be holding their stomach area.

Signs and Symptoms of the Circulatory System

- Increased heart rate.
  - A child may think their heart is pounding in their chest along with a fast pulse.
- Decrease in blood pressure.
  - If blood vessels get bigger during anaphylaxis, it may be hard to feel a child's pulse.
- Cool, clammy skin.
  - While it is normal to sweat while exercising or in the heat, a child with what feels sweaty but also cool skin is a sign of anaphylaxis.

What is the difference between an allergic reaction and anaphylaxis?

- With an anaphylactic reaction, there will be symptoms involving two or more body systems at the same time.
- With an allergic reaction, you will have one type of symptom – either have a rash OR be itchy OR have an upset stomach.

How long does anaphylaxis last?

Symptoms normally peak within a half-hour of exposure, but they can last for several hours. About 20% of the time**,** symptoms can be controlled with treatment, but they may come back.

Sometimes there can be a biphasic reaction which is defined as a rebound reaction. Biphasic means the symptoms come in two phases. There may be recovery from the first reaction, but symptoms come back. This can occur up to 12 hours after the first symptoms. The rebound may be mild, but there may still be a need for a second dose of epinephrine.

Epinephrine is a relatively quick-acting medication. It begins to work immediately and wears off quickly. The side effects don't last very long. Most of the side effects should start to resolve within about 30 minutes and fully disappear within a few hours.

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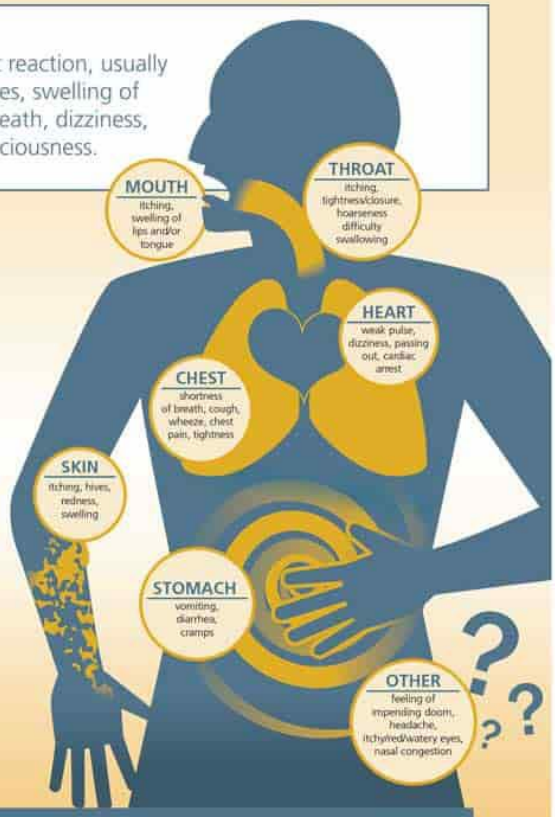
What is Anaphylaxis? | Allergy & Asthma Network

Anaphylaxis is a severe, life-threatening allergic reaction, usually to food, insect venom, medication or latex. Symptoms include: hives, swelling of lips and/or tongue, coughing, wheezing, vomiting, shortness of breath, dizziness, chest tightness, headache, weak pulse, confusion and loss of consciousness.



Allergy & Asthma NETWORK

YOU NEED 2

ALWAYS CARRY 2 EPINEPHRINE AUTO-INJECTORS

1st line of treatment = Epinephrine

Why "You Need 2"

15-30% of all anaphylaxis patients experience a 2nd reaction (called a biphasic reaction)

Almost **20%** of children experiencing a food-related anaphylaxis reaction will experience a 2nd reaction

5 MINUTES to **15 MINUTES**

Keep Watching

A **2nd reaction** can occur within **5 to 15 minutes** after the 1st dose is administered.

It can also occur between **8 and 72 hours** after the 1st reaction.

Any delay of treatment = Greater chance for hospitalization + Greater risk for death

Don't delay anaphylaxis treatment!

Sources:
- Guidelines for the Diagnosis and Management of Food Allergy in the United States – National Institute of Allergy & Infectious Diseases (NIAID)
- Use of Multiple Doses of Epineprhine in Food-Induced Anaphylaxis in Children – Jarvinen, K.; Sicherer, S.; Sampson, H.; Nowak-Wegrzyn, A. – Journal of Allergy and Clinical Immunology

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What is Epinephrine?

Epinephrine, also known as adrenaline, is both a hormone and a medication. A person's adrenal glands produce epinephrine, which helps to regulate organ functions. It is typically released when the body is under stress. It is part of the fight or flight response. When an epinephrine injection is given, it does all of this simultaneously. It also gives some people the feeling of being hyper or anxious.

Epinephrine should be administered promptly at the first sign of anaphylaxis. It is safer to administer epinephrine than to delay treatment for anaphylaxis. Epinephrine is the only medication that can reverse symptoms. It is crucial to use epinephrine first and epinephrine fast. Then seek prompt treatment in your nearest emergency room.

Epinephrine should be stored at room temperature (between 59-86 degrees F) in a dark area. The epinephrine should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired injectable epinephrine device or those with discolored solution or solid particles should not be used. Personnel should be familiar with the type of injectable epinephrine device maintained by the school and its use.

What does Epinephrine do?

Epinephrine has different effects on different parts of the body which are normal and expected including:

- Heart — it causes the heart to pump faster and harder. This raises your blood pressure and circulates blood more quickly throughout the body.
- Lungs and airways — your breathing becomes deeper and faster. It dilates the airways and may reduce swelling.
- Eyes — it causes the pupils in your eyes to dilate.
- Skin — it becomes pale, as blood is diverted to your major organs and muscles.
- Muscles — they have increased blood flow.

How to Use an Auvi-Q You Tube Video

How to Use an Epi-Pen YouTube Video

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For a student with specific orders on file: (written individual health plan), follow the student's individually prescribed emergency action plan as it relates to a known life-threatening allergy and/or known history of anaphylaxis. Note: For some students with known potential for life- threatening allergic reactions, the individual health plan may call for administration of injectable epinephrine after exposure to a known allergen and before symptoms of anaphylaxis may be present.

For a student without specific orders on file: Based on symptoms observed, determine that an anaphylactic reaction is occurring.

Go to the student. Never send a student to the health room alone or leave a student alone. Do not move a student who is in severe distress.

1. Act quickly. Only a few symptoms may be present. The severity of symptoms can change rapidly.
2. Call 911 for emergency medical services (EMS)
3. Direct someone to call the school nurse or front office.
4. Direct someone to notify the child's parents.
5. Place student on his/her back, if possible, with feet elevated, unless upper airway obstruction is present, or the patient is vomiting.
6. Determine the proper dose of epinephrine.
    - Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
        - In adults, administer a 0.3 mg intramuscular dose using an injectable epinephrine device.
        - In children, administer a standard dosage using the Jr. injectable epinephrine device.
            - For children 33 lbs. to <65 lbs. administer the 0.15 mg injectable epinephrine device (FDA product insert). The 0.15mg injectable epinephrine device can also be used for children 7.5 kg (16.5 lbs.) to <15 kg (33 lbs.) when other alternatives are not available (American Academy of Pediatrics).
            - For children ≥66 lbs. administer the 0.30 mg injectable epinephrine device (FDA product insert).
        - Administer in the mid-outer thigh (through clothing if necessary).

Administer the injectable epinephrine:

1. Take off the cap.
2. Press the tip firmly on the thigh at a perpendicular (right) angle.
3. Swing and push the injectable epinephrine device firmly until you hear a click.
4. Hold firmly for 10 seconds.
5. Remove the injectable epinephrine device.
6. Massage area for 10 seconds.
7. Begin monitoring airway and breathing.
8. For a severe reaction consider keeping the student lying on his/her back with legs raised.
9. Remain with the student and reassure him or her as needed.
10. A second dose of epinephrine may be given 5 minutes or more after the first if symptoms persist or recur.
11. Document student's name, date and time epinephrine was administered on the used injectable epinephrine device and give to Emergency Medical Services (EMS), when EMS arrives, so that the information will accompany the student to the emergency department.
12. Even if symptoms subside or go away, EMS must still be summoned to respond, and the student must be evaluated by a physician. A delayed or secondary reaction may occur up to several hours later.
13. Document the incident and complete the school incident report.
14. Replace epinephrine stock medication as appropriate.

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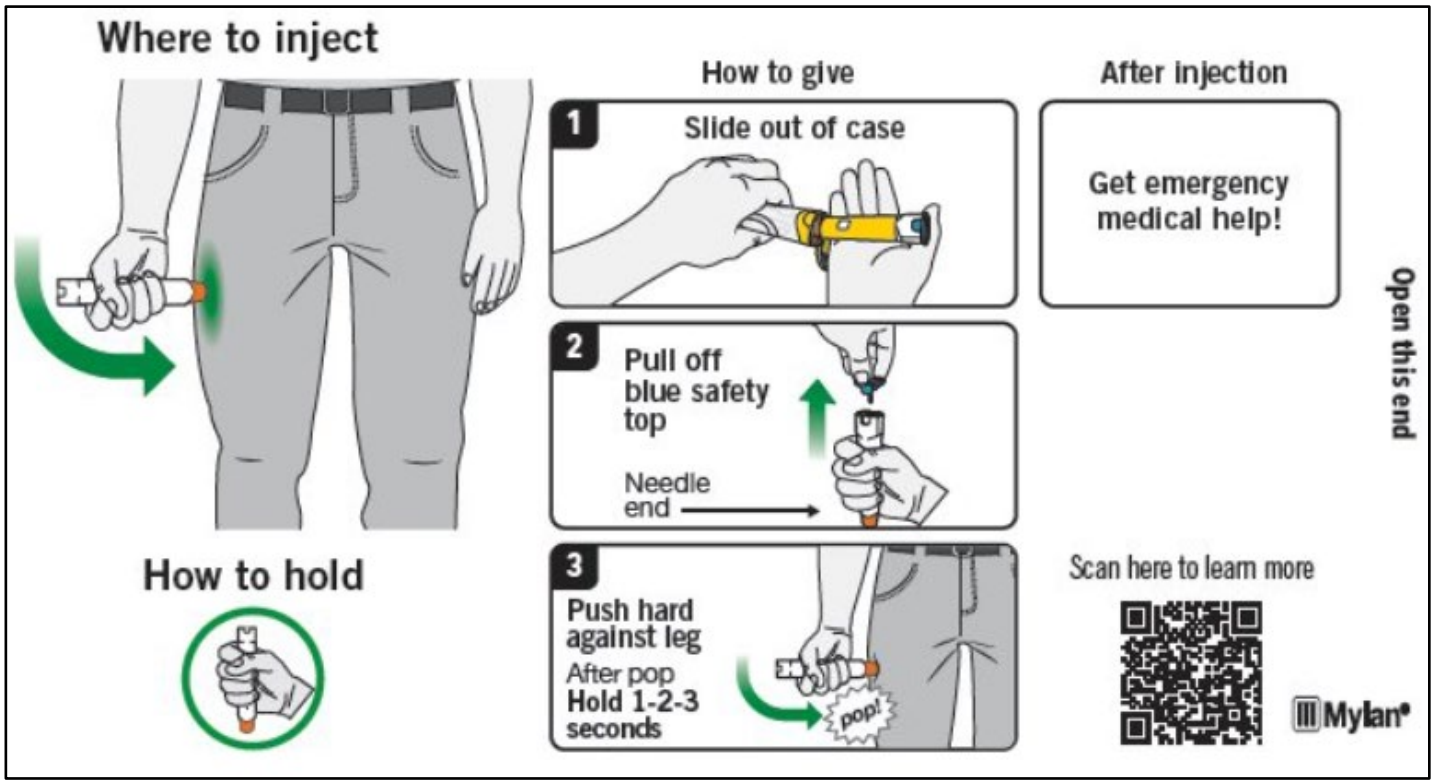

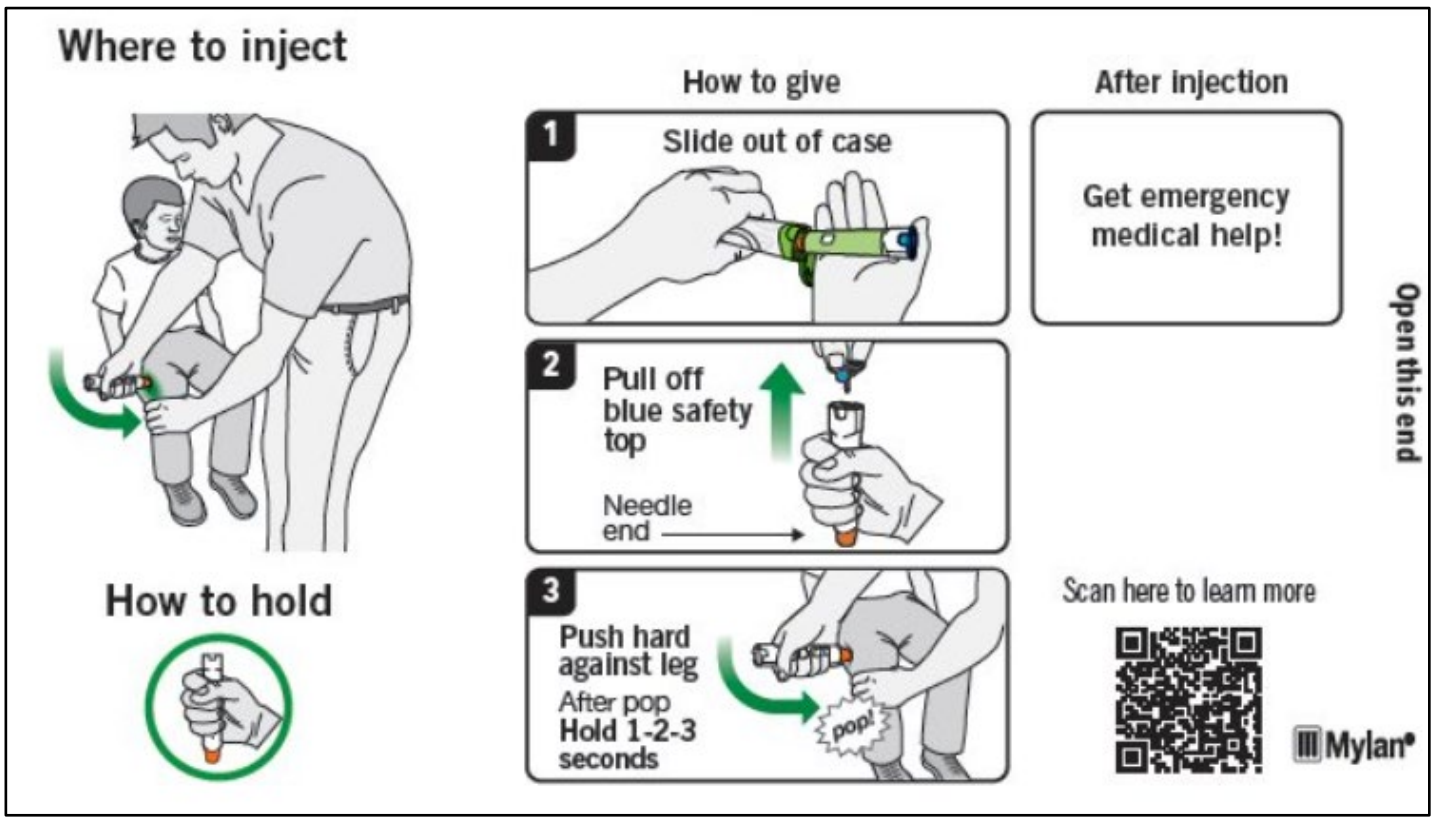

Note the time that the epinephrine is administered. For questions regarding dosage or timing of the injectable epinephrine device brand being used, please see product instructions developed by the manufacturer.

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Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for at least four hours is advised, even after complete resolution of symptoms.

How long do side effects of epinephrine last?

Epinephrine is a relatively quick-acting medication. It begins to work immediately and wears off quickly. The side effects don't last very long. Most of the side effects should start to resolve within about 30 minutes and fully disappear within a few hours.

When to give a second dose of epinephrine?

A second dose of epinephrine should be given if symptoms persist 5-15 minutes after the first dose is administered. Sometimes symptoms reemerge between 8 and 72 hours after the first injection. These are called biphasic anaphylactic reactions.
You should call 911 or go to your nearest emergency room for medical assistance anytime you administer epinephrine.

Check expiration dates. Epinephrine auto-injectors should be replaced as soon as they expire. Check the date on devices monthly.

Epinephrine_Treatments_2019_01_poster-1024x791.jpg (1024×791) (allergyasthmanetwork.org)

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How should epinephrine auto-injector be stored?

Store epinephrine auto-injectors as close to room temperature as possible. Leaving them in extremely hot or cold temperatures can make the epinephrine ineffective or cause the injector to malfunction. Do not store them in a car or in a refrigerator.

Keep auto-injectors out of direct sunlight. This can cause the epinephrine to oxidize (combine with oxygen, changing the makeup of the drug) and become ineffective. Oxidized epinephrine will appear dark or have solid particles in it. Epinephrine can also oxidize on its own over time, so check your device regularly to be sure the liquid inside is clear.

Common Epinephrine Delivery Devices

- EPIPEN® (epinephrine injection, USP) Auto-Injector| Official Website
  - Instructions for use of the EpiPen® and EpiPen Jr® are found at How to use EpiPen
    - Epinephrine in Schools | EpiPen4Schools®
    - The EPIPEN4SCHOOLS program provides up to four free EPIPEN (epinephrine injection, USP) or EPIPEN JR (epinephrine injection, USP) Auto-Injectors in the form of two EPIPEN 2-PAK® cartons, two EPIPEN JR 2-PAK® cartons or one 2-Pak of each kind along with EPIPEN Trainers and a detailed training video, to qualifying public and private kindergarten, elementary, middle, and high schools in the US. Schools may receive the authorized generic versions of EPIPEN and EPIPEN JR.
- Generic EpiPen®
  - EPIPEN® (epinephrine injection, USP) Auto-Injectors| Authorized generics
  - Teva's Epinephrine Auto-Injector – Using the device (tevaepinephrine.com) Instructions for use of generic or Teva® epinephrine auto-injector.
- HIGHLIGHTS OF PRESCRIBING INFORMATION: These highlights do not include all the information needed to use EPIPEN® and EPIPEN Jr® safely and effectively. See full prescribing information for EPIPEN and EPIPEN Jr. EPIPEN® (epinephrine injection), for intramuscular or subcutaneous use EPIPEN Jr® (epinephrine injection), for intramuscular or subcutaneous use Initial U.S. Approval: 1939 (nih.gov)

- AUVI-Q® (epinephrine injection, USP)auto injector is pocket-sized device that can be used to self-administer epinephrine in response to symptoms of anaphylaxis. It has a voice prompt that gives step-by-step instructions on the administration of the medication.
  - Instructions on use found at How to Use AUVI-Q® (epinephrine injection, USP).
- SYMJEPI® (epinephrine) Injection, is a syringe with the correct dose of epinephrine already loaded. The needle must be inserted, and the plunger depressed to deliver the medication. It is also available in both 0.15 mg dose for children 33-65 lbs. and 0.3 mg for people over 66 lbs.
  - Instructions on how to use found at SYMJEPI® (epinephrine) Injection | How to Use SYMJEPI | Official Website.

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References and Resources

Allergy and Asthma Network

- Allergy & Anaphylaxis: A Practical Guide for Schools and Families
- Anaphylaxis = Epinephrine: Treating a Severe Allergic Reaction (allergyasthmanetwork.org)
- Anaphylaxis | Allergy & Asthma Network (allergyasthmanetwork.org)
- What is Epinephrine? | Allergy & Asthma Network (allergyasthmanetwork.org)

American Academy of Allergy Asthma & Immunology (AAAAI)

- Anaphylaxis Symptoms, Diagnosis, Treatment & Management | AAAAI
- Stock Epinephrine Toolkit for Schools (aaaai.org)

American Academy of Pediatrics

- Allergy and Anaphylaxis Management in Schools (aap.org)
- Epinephrine for First-aid Management of Anaphylaxis | Pediatrics | American Academy of Pediatrics (aap.org)
- Guidance on Completing a Written Allergy and Anaphylaxis Emergency Plan | Pediatrics | American Academy of Pediatrics (aap.org)
    - AAP_Allergy_and_Anaphylaxis_Emergency_Plan.pdf

Centers for Disease Control and Prevention

- Food Allergies in Schools
- Food Allergies in Schools Toolkit
- Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs

Food Allergy and Anaphylaxis Network (FAAN)

- Back-to-School Resource Hub | Food Allergy Research & Education
- Food Allergy & Anaphylaxis Emergency Care Plan - FoodAllergy.org

Food Allergy Research and Education

- Food Allergy and Anaphylaxis Emergency Care Plan
- Microsoft Word - Anaphylaxis Emergency Action plan updated 2020_AM.docx (aaaai.org)

Kentucky Department of Education

- Student Health Services - Kentucky Department of Education
- Health Services Reference Guide - Kentucky Department of Education
- Medication Administration Training Program - Kentucky Department of Education Updated 2021

National Association for School Nurses (NASN)

- Allergies and Anaphylaxis - National Association of School Nurses (nasn.org)
    - Sample Planning Checklists
    - Sample Policy
    - Sample Practice Forms
    - School Personnel Training Resources
    - Education Resources