



Risk Management Guidelines

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Subject: Epinephrine Pen Guideline

[District Letterhead]

Anaphylaxis Treatment Protocols and Standing Orders

For use in Public Schools for persons without individual physician written orders.

DEFINITION: Anaphylaxis is a sudden, severe, potentially fatal, systemic allergic reaction that can involve various areas of the body (such as the skin, respiratory tract, gastrointestinal tract, and the cardiovascular system). Onset may be sudden (generally within minutes to two hours after contact with the allergy-causing substance, but may occur up to four hours after contact). Allergic reactions may be mild to life threatening. While anyone may experience anaphylaxis, individuals with asthma, eczema, or hay fever are at greater relative risk. Patients with asthma are those most at risk for life-threatening anaphylaxis events.

Severe, even fatal reactions can occur in previously unidentified individuals.

RECOMMENDATIONS:

- It is recommended that at least two (2) epinephrine auto-injectors be available in schools for anaphylaxis emergencies.
- All epinephrine auto-injector should be stored according to manufacturer's directions to maintain effectiveness and in a **clearly labeled, easily accessible cabinet.**
- An epinephrine auto-injector should be considered for first aid kits for field trips and/or school events.
- Expiration dates on epinephrine auto-injector should be monitored and documented on an appropriate log. The shelf-life of an epinephrine auto-injector is approximately one to one and a half years. The fluid should be clear and colorless. Discard if the fluid has turned brown or is cloudy.
- All individuals receiving emergency epinephrine should have 911 summoned immediately even if symptoms appear to have resolved.

PERSONNEL:

- The school nurse (or other qualified supervisor of health, *Education Code* sections 44871-44878) assigns, monitors, and supervises the annual training of unlicensed personnel in the administration of epinephrine auto-injectors for allergic, life threatening emergencies.
- All designated staff who are trained to administer the epinephrine auto-injectors should have current cardiopulmonary resuscitation (CPR) certification (per ed code 49417).
- Designated and trained school personnel serve under the direct or indirect supervision of the credentialed school nurse (or other qualified supervisor of health).

COMMON CAUSES:

Food
Insect stings
Medication
Latex

LESS COMMON CAUSES:

Food-dependent exercise-induced anaphylaxis - individual eats a specific food and exercises within three to four hours after eating.
Idiopathic anaphylaxis - unknown cause

ANAPHYLACTIC SYMPTOMS (Sudden onset or progression over a few hours)

May include any or many of the following:

- Tingling sensation, itching, or metallic taste in mouth.
- Hives or generalized flushing, itching, or redness of the skin.
- Nasal congestion or wheezing (asthma-like symptoms).
- Swelling of the throat, lips, tongue, and around the eyes.
- Feeling of apprehension, agitation, sweating, weakness or shock.

If any of the following symptoms occur, administer EPINEPHRINE AUTO-INJECTOR IMMEDIATELY & CALL 911

***Difficulty Breathing or wheezing**

***Difficulty Swallowing, swelling of the throat, throat tightness, or voice changes**

<ul style="list-style-type: none"> • Abdominal cramping, nausea, vomiting, or diarrhea. • Drop in blood pressure and paleness. • Throbbing heart beat/throbbing in ears/dizziness/headache. • Throat tightness/change of voice. 	*Fainting or Loss of Consciousness, shock, or drop in blood pressure
	*Convulsions

MANAGEMENT OF ANAPHYLAXIS

ESSENTIAL STEPS	KEY POINTS AND PRECAUTIONS
1. Determine if anaphylaxis has occurred. (If suspected, treat as anaphylaxis.)	1. Anaphylaxis usually occurs right after insect sting, injection of medication, or ingestion of foods, such as peanuts, nuts, fish, eggs or milk. (Any food could potentially cause a reaction.)
2. If anaphylaxis symptoms occur. GET epinephrine auto-injector. SECONDS COUNT! Direct someone to activate the emergency medical system (EMS) 911.	2. Stay with the victim. Get or direct someone to get epinephrine auto injector. a. Have others notify EMS, school nurse, parents, and school administrator immediately.
3. Have the victim sit down. Calm and reassure the victim.	3. Avoid moving the victim. Calming reduces the distribution of the allergen in the body.
4. Prepare to administer the epinephrine auto-injector Under 66 lbs, use 0.15 mg Over 66 lbs, use 0.3 mg	4. The epinephrine auto-injector acts immediately, so do not delay in administering it. Make sure 911 has been called.
5. Epinephrine auto-injector Administration Procedure: a. Pull off the Safety Cap b. Firmly push the OUTER THIGH c. You will feel or hear a sound. d. Hold in place for 5-10 seconds, then remove. e. Call 911, if not previously called.	5. The epinephrine auto-injector can be injected through the clothing. If removing the clothing is not possible or will significantly delay the treatment. After receiving epinephrine, the victim may feel his/her heart pounding. This is a normal reaction to the medication. Do not let victim stand. Victim should remain in position of comfort, either sitting or lying down.
6. NOTE: If the anaphylactic reaction is due to an insect sting, remove the stinger ASAP after administering the epinephrine auto-injector. a. Apply an ice pack to the sting area.	6. Remove the stinger quickly by scraping with a fingernail or plastic card. a. Do NOT push, pinch, or squeeze, or further imbed the stinger into the skin. This may cause more venom to be injected into the victim.
7. Monitor airway and breathing. Observe for signs of shock.	7. If breathing stops-begin CPR IMMEDIATELY. a. Maintain the victim's body temperature. Cover the victim with a blanket, if needed.
8. Have someone make copy of emergency card for paramedics.. Give expended epinephrine auto-injector to paramedics.	8. When paramedics arrive, give a factual report about the incident, including the time the epinephrine auto-injector was administered.
9. If symptoms continue or reoccur and the paramedics do not arrive, re-inject the victim (with a new epinephrine auto-injector) 5-15 minutes after the initial injection.	9. Continue to monitor the airway and the victim's breathing.
10. Follow-up medical care should be obtained immediately in an emergency room.	10. A second delayed (bi-phasic) reaction may occur up to six hours after the initial anaphylaxis.
11. Document the incident, date and time the epinephrine auto-injector was administered, the victim's response, and additional pertinent information.	11. Complete any appropriate paper work. Make sure school nurse is notified, if not present.

FOLLOW-UP

1. Refer ALL anaphylaxis cases to the victim's physician.
2. Recommend that the parents discuss with physician about avoiding triggers and prescribing an epinephrine auto-injector.
3. Complete the required documentation.

Standin Orders and Protocols for Anaphylaxis Treatment Procedure Approvals

SIGNATURES*	NAMES (print or type)
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Physician:	
X	Date
School Nurse/Supervisor of Health:	
X	Date
Administrator	
X	Date



Frequently Asked Questions Regarding SB 1266 Emergency Epinephrine Auto-injectors

1. Will this bill REQUIRE all school districts to provide emergency epinephrine auto-injectors'!

According to 49414 (a) "School districts, county offices of education, and charter schools shall provide emergency epinephrine auto-injectors to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction."

2. When will this bill be enacted and when do schools need to be in compliance?

The law takes effect on January 1, 2015. The State Superintendent's office will be making final arrangements for implementation and the final timeline is still being determined.

3. What does the law state regarding 'trained volunteer'?

Volunteer means an "employee who has volunteered to administer an emergency epinephrine auto-injector, has received training in the use of an epinephrine auto-injector, and has been designated by the school as a trained volunteer who will administer epinephrine auto-injector to a pupil if the pupil is suffering or reasonably believed to be suffering from anaphylaxis."

4. How will volunteers be identified?

"A school district, county office of education, or charter school shall distribute a notice at least once per school year to all staff that contains the following information: A description of the volunteer request stating that the request is for volunteers to be trained to administer an epinephrine auto-injector as well as a description of the training the volunteer will have to undergo."

5. What constitutes 'training'?

There are current guidelines regarding epinephrine auto-injectors in place on the California Department of Education website, but they will be updated per the legislation. "The (State) Superintendent shall consult with organizations and providers with expertise in administering epinephrine auto-injectors and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the American Academy of Allergy, Asthma and Immunology, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, Food Allergy Research and Education, the California Society of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, the Stanford Allergy Center, and others. Every five years, or sooner as deemed necessary by the (State) Superintendent, the Superintendent shall review minimum standards of training for the administration of epinephrine auto-injectors. Training established pursuant to this subdivision shall include all of the following:

- Techniques for recognizing the symptoms of anaphylaxis
- Standards and procedures, for the storage, restocking and emergency use of emergency epinephrine auto-injectors.
- Emergency follow up procedures, including calling EMS
- Recommendation on the necessity of CPR certification
- Instruction on how to determine whether to use an adult epinephrine auto-injector or a junior epinephrine auto injector-which shall include consideration of grade level or age as a guideline of equivalency for appropriate pupil weight determination.
- Written material covering the information"



Frequently Asked Questions Regarding SB 1266 Emergency Epinephrine Auto-injectors

6. How many staff must be trained?

"Each school may designate one or more school personnel on a voluntary basis to be trained." However, CSNO strongly feels that a minimum number of staff trained should be at least 2-3 per site.

7. How frequently must the staff be trained?

"Volunteer personnel shall receive initial and annual refresher training." CSNO believes that school nurses and/or qualified supervisors of health should determine the frequency of training, with a minimum of at least once a year.

8. Who provides the training? :

Training is provided either by the school nurse or other qualified person designated by the physician or surgeon employed or contracted by the LEA, the medical director of the local health department or the local emergency medical services director'.

9. Is there protection for volunteers who act in an emergency and administer the emergency epinephrine auto-injector?

Yes, "a school district, county office of education or charter school shall ensure that each employee who volunteers will be provided defense and indemnification by the school district, county office of education or charter school for any and all civil liability".

10. Are the emergency epinephrine auto-injectors required to be available for off-site school activities?

"The emergency epinephrine auto-injectors are furnished exclusively for use at a school district site, county office of education or charter school." The law does not address field trips or other off site school activities. CSNO recommends that school nurses work with their districts to develop policies and procedures that address activities outside of the school site, considering school nurse staffing and other challenges with regards to evenings and weekends.

11. Who is responsible for obtaining the prescription?

"A school nurse or if not available, a school administrator or employee who has volunteered shall obtain from a physician employed by or contracting with the LEA, the medical director of the local health department or the local emergency medical services director." (Suggestions include contracting with your Workers Comp clinic or physician, your sports physician, or local physician such as an ED or other practitioner who is willing to contract with the school district to review Standing Orders and write a prescription).

12. If the prescription is "non-patient specific", whose name should be on it?

The current law doesn't specify how the emergency epinephrine auto-injectors are labeled. This would be the prescribing physician and/or pharmacy's decision. Some may wish to have the school's name on the prescription and on the label attached to the container in which the epinephrine auto-injectors are packaged. However, the current program that provides free epinephrine auto-injectors are provided with no specific labeling/name information.

13. How many emergency epinephrine auto injectors must a school obtain?

"An elementary school should obtain *at minimum*, one regular epinephrine auto-injector and one junior epinephrine auto-injector. For junior and high schools, one regular epinephrine auto injector, unless they have students who meet the criteria for a junior epinephrine auto injector." However, CSNO supports having at least 2 epinephrine auto-injectors per site.



Frequently Asked Questions Regarding SB 1266 Emergency Epinephrine Auto-injectors

14. If the emergency epinephrine auto injector is used, when does it need to be restocked by?

"If an emergency epinephrine auto-injector is used, it shall be restocked as soon as reasonably possible, but no later than 2 weeks after the use." See <http://www.epipen4schools.com> for the replacement process through Mylan Specialty Inc.

15. Is the use of an emergency epinephrine auto-injector required to be reported-and to whom?

Currently, the reporting portion is still unclear (whether the use will need to be reported to the County Office or State Department of Education), but CSNO recommends that school nurses work with their school district to develop/implement documentation procedures that ensure that appropriate care and follow up was taken and that the medication was restocked in a timely manner). Additionally, CSNO would like the information to be reported to the CSNO/NASN data points located on the CSNO website (<http://www.csno.org/index.html>).

16. Which epinephrine auto-injector should a school get?

The statute does not specify a particular "brand" of epinephrine auto-injector-however the prescribing physician may indicate which epinephrine auto-injector to dispense. There are a number of epinephrine auto-injectors that have been approved by the FDA and are available, with a prescription for the management of life threatening allergies. The devices operate in different ways, so it is critically important that schools and pharmacies ensure that the designated school personnel are trained to use the specific epinephrine auto-injector that is prescribed and dispensed. Different auto-injectors have different operational instructions. When an auto-injector is needed, seconds matter.

17. Is there funding for the emergency epinephrine auto-injectors?

Currently, (and they have assured us that they will continue) Mylan Specialty Inc., the international pharmaceutical company the marketer and distributor of EpiPen® and EpiPen Jr®, will provide 4 FREE Epi pens (either regular or junior) for EACH school site through www.epipen4schools.org program. A school district needs to provide them with a written prescription for the total number of Epi pens requested. In the event that an Epi Pen is used to respond to an allergic emergency (anaphylactic event), qualifying schools are eligible to receive a replenishment order of EpiPen® and EpiPen Jr®, auto-injectors prior to their annual eligibility date at no additional cost. A report of the incident is required.

18. Are there any current resources for Standing Orders, Board Policies, additional information, etc?

Yes, CSNO has a link that will provide templates and resources <http://www.csno.org/school-nurse-resources.html>. Scroll down to Allergies and Anaphylaxis. Another source is the Mylan Specialty Inc. through the EpiPen4schools program <https://www.epipen4schools.com/Resources/>

Epinephrine Standing Order Protocol

Request for Prescription/Annual Reauthorization

I, the undersigned Physician, for the purpose of facilitating the use of Epinephrine in the case of Potentially Life-Threatening Allergic Reactions (anaphylaxis) in individuals and in compliance with all applicable state laws and regulations, issue this Epinephrine Standing Order Protocol ("Protocol") on the following terms:

Physician License: I represent that I (a) am licensed to prescribe legend drugs in this state as set forth below; (b) am qualified to practice medicine in this state; and (c) am in good standing with the appropriate professional licensing board.

Epinephrine: This Protocol constitutes my standing order for the treatment of anaphylaxis and the use of Epinephrine in emergency situations as further described below in a school setting.

Delegation: I, the undersigned Physician, delegate authority to all appropriate medical and school personnel employed by or acting on behalf of the below described school system.

Issued to: -----

Name of School/ District

Street Address

City, Zip Code

Standing Order: All appropriate medical and school personnel (including, but not limited to, any Registered Nurse) employed by or acting on behalf of the school system may administer Epinephrine via an undesignated Epinephrine auto-injector to an individual using professional judgment if an individual is experiencing a potentially life-threatening allergic reaction, such as anaphylaxis.

Emergency Treatment Procedures: The following treatment Protocol will be utilized to manage anaphylactic reactions. Anaphylaxis is described as the sudden onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse. In the event of a serious adverse reaction, including anaphylaxis, the following shall be done:

1. **Symptoms:** If itching and swelling are confined to a localized area, observe the patient closely for the development of generalized symptoms. If symptoms are generalized, activate the emergency medical system (e.g., call 911). This should be accomplished by a second person while the individual is being evaluated and managed by the first person.

2. **Dosage:** If conditions of anaphylaxis are developing or present themselves, administer Epinephrine USP, 1 mg/mL, (1:1000) as epinephrine auto-injector, EpiPen, intramuscularly into the antero-lateral aspect of the thigh (through clothing if necessary) according to the manufacturer's recommendation.

For individuals less than 66 pounds, use one EpiPen Jr. (0.3 mL epinephrine injection, USP, 1:2000) auto-injector to deliver 0.15 mg of epinephrine injection, USP.

For individuals 66 pounds and greater, use one EpiPen (0.3 mL epinephrine injection, USP, I: 1000) auto-injector to deliver 0.3 mg of epinephrine injection USP.

3. **Monitoring:** Closely monitor the individual until EMS arrives. Perform CPR and maintain airway, if necessary. Keep the individual in a supine position unless he/she is having difficulty breathing. If having difficulty breathing the individual's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness.

5. **Frequency:** Monitor vital signs frequently. If EMS has not arrived and symptoms persist, a repeat dose of Epinephrine auto-injector every 5-20 minutes after the first dose may be administered.

6. **Referral:** The individual must be referred to a physician for medical evaluation, even if symptoms resolve completely. Symptoms may recur after the Epinephrine wears off, as much as 24 hours later.

7. **Documentation:** The details of the incident must be immediately documented in a writing.

8. **Notification:** Within 4 hours, the school must notify the individual's parent, guardian or caretaker and must notify the individual's primary care physician of the anaphylactic reaction.

Note: Epinephrine Auto-Injectors are available in 0.3mg dose (EpiPen I:1000) and 0.15mg dose (EpiPen Junior I: 1000). Using two 0.15 doses to obtain 0.3mg dose is permissible.

In every case, emergency services must be contacted as soon as possible by calling 911.

Please review the attached prescription:

Effective Date: -----

Physician Signature: -----

Physician Name (printed): -----

Physician Contact Number: -----

Physician Address: -----

Physician State of License: -----

Physician State License Number: -----

Strength	Quantity Requested
0.3mg EpiPen 2-Pak	
0.15mg EpiPen 2-Pak	

**Please note there are two auto injectors per EpiPen 2-Pak or EpiPenJr 2-Pak. Example: If you wish to order 100 EpiPen Auto-Injectors and 80 EpiPenJr Auto-injectors, put the number 50 in quantity requested box next to the 0.3 mg EpiPen 2-Pak and 40 in the quantity requested box next to the 0.15 mg EpiPenJr 2-Pak.*

[District Letterhead}

Epinephrine Indemnity Acknowledgment

Pursuant to Education Code section 494 14(j), as a volunteer of the _____ *[Identify District or County Office of Education or Charter School]* trained to use epinephrine auto-injectors to provide emergency medical aid, you are hereby advised that you are protected by the following provisions of California law regarding civil liability for your actions in the course of scope of you serving as a volunteer in this capacity.

California law provides specific legal obligations for an employer to defend and indemnify you in litigation against you, and these obligations are set forth in separate statutes in California's Government Code.

The obligation to provide a defense for you if you are sued as a result of volunteer related incidents is set forth in Government Code section 995, which provides in part:

Except as otherwise provided in Sections 995 2 and 995 4, upon request of an employee or former employee, a public entity shall provide for the defense of any civil action or proceeding brought against him, in his official or individual capacity or both, on account of an act or omission in the scope of his employment as an employee of the public entity.

The obligation to indemnify you against a civil judgment or award is set forth in Government Code section 825(a), which provides in part:

Except as otherwise provided in this section, if an employee or former employee of a public entity requests the public entity to defend him or her against any claim or action against him or her for an injury arising out of an act or omission occurring within the scope of his or her employment as an employee of the public entity and the request is made in writing not less than 10 days before the day of trial, and the employee or former employee reasonably cooperates in good faith in the defense of the claim or action, the public entity shall pay any judgment based thereon or any compromise or settlement of the claim or action to which the public entity has agreed.

By signing below, I acknowledge receipt of this notification.

Employee's Signature

Employee's Printed Name

Date: -----

cc: Employee's Personnel File

MEDICATION AT SCHOOL FORM

Student Name: _____

Date of Birth: __ _

Grade _

Parent/Guardian Name: _____

Phone: _____

Education Code 49423 defines certain requirements for the administration of medication in the school setting. A student can be allowed medication in the school setting if a Medication at School form has been completed and signed by parent/guardian and physician. This authorization will remain in effect for one year, unless terminated by parent earlier. If there is a change in the student's health status or medication regime the parent must notify the school immediately. Medication must be sent to school in the original pharmacy container and clearly labeled with student's name. No medications (including over the counter) will be given at school without a current doctor prescription.

PARENT REQUEST

The undersigned, which is a parent/guardian of the above named student, requests that the school nurse or designated school personnel assist the pupil, when necessary, in the matter set forth by the physician's orders. I hereby consent to self-administration, if authorized by the physician. Furthermore, I consent to appropriate school personnel consulting with the student's physician regarding the medication, if necessary. Parent will hold harmless school personnel with regards to their child's medication at school.

Signature of Parent/Guardian: _____

Date: _____

PHYSICIAN'S ORDERS

Diagnosis/Condition for which the medication is to be given: _____

Medications: _____ Dosage: _____

Method of Administration: _____ Time Limit: _____

Possible side Effects: _____

Asthma Inhalers/Auto Injectable Epinephrine:

Does the student need to carry an inhaler or auto injectable epinephrine on campus?

Yes _____ No _____

I have instructed the student in the proper way to use his/her or inhaler or auto-injectable epinephrine, including proper administration technique. It is my professional opinion that the student is able to self-administer the medication and should be allowed to carry and use the inhaler or auto-injectable epinephrine on campus.

Physician's Name (Printed): _____

Date: _____

Physician's Signature: _____

Phone: _____

School Nurse: _____

Date: _____

School Name: _____ Phone: _____

Fax: _____

EpiPen4Schools™ Program Update Fact Sheet

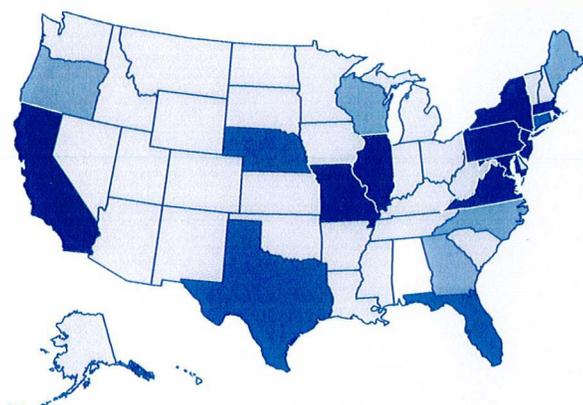
Since Mylan Specialty L.P. launched the EpiPen4Schools™ (www.EpiPen4Schools.com) program in August 2012, more than 20,000* schools across the country have elected to participate.¹ The program offers four free EpiPen® (epinephrine) or EpiPen Jr® (epinephrine) Auto-Injectors, upon qualification, which includes having a valid prescription, to public and private kindergarten, elementary, middle and high schools in the U.S. The products are available in the form of two EpiPen 2-Pak® cartons, two EpiPen Jr 2-Pak® cartons, or one 2-Pak of each kind.

EpiPen4Schools was created to help schools have improved access to epinephrine in the event a person experiences a life-threatening allergic reaction (anaphylaxis) at school. Avoidance of allergic triggers is the critical first step to prevent a serious health emergency; however, accidental exposure may still happen.^{2,3} For that reason, access to epinephrine is important because it is the only first-line treatment for life-threatening allergic reactions.⁴

Each school should have a comprehensive anaphylaxis action plan that emphasizes avoidance of the allergens. The plan also should include awareness of the risks, preparedness for an emergency and access to two epinephrine auto-injectors and immediate medical care.^{5,6,7}

A survey conducted in 109 Massachusetts school districts from 2001 to 2003 evaluating the use of epinephrine for anaphylaxis management in schools found that up to 24% of anaphylactic reactions occurred in individuals who were not known by school personnel to have a prior history of life-threatening allergies.⁸

Thousands of Schools Nationwide are Receiving Free EpiPen® (epinephrine) Auto-Injectors Through the Mylan Specialty EpiPen4Schools Program



*As of January 2013

Number of schools that are participating in EpiPen4Schools program as of January 2013



The EpiPen4Schools program underscores Mylan Specialty's ongoing commitment to address barriers and help schools have improved access to epinephrine in the event a person experiences anaphylactic reaction at school. For the millions of children in the U.S. with potentially life-threatening allergies—as well as others who are determined to be at increased risk—it is critically important for schools to have epinephrine auto-injectors on hand to treat anaphylaxis should it occur.

Indications

EpiPen® (epinephrine) 0.3 mg and EpiPen Jr® (epinephrine) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen and EpiPen Jr are intended for immediate self administration as emergency supportive therapy only. Seek immediate emergency medical treatment after use.

Important Safety Information

EpiPen Auto-Injectors contain a single dose of epinephrine, which you inject into your outer thigh. **DO NOT INJECT INTO YOUR VEIN, BUTTOCK, FINGERS, TOES, HANDS OR FEET.** In case of accidental injection, please seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Please see additional Important Safety Information on next page.

Please see accompanying full Prescribing Information and Patient Information.

EPIPEN 2-PAK® EPIIPENJr® 2-PAK®
(Epinephrine) Auto-Injectors 0.3/0.15mg



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epipen.com

EpiPen4Schools™ Program Update Fact Sheet

How to Participate in EpiPen4Schools

Eligible schools can participate in the EpiPen4Schools program by having a school nurse or other authorized school representative visit www.EpiPen4Schools.com, complete and print the order and certification form, and fax or email the form with a valid prescription to 1-973-718-4328 or info@bioridgepharma.com.

To learn more and participate in the program, visit www.EpiPen4Schools.com.

Additionally, Mylan Specialty offers a discount program through which schools can purchase, upon qualification, which includes having a valid prescription, EpiPen 2-Pak cartons and EpiPen Jr 2-Pak cartons at a discounted price.

There is no requirement for a school to purchase additional EpiPen Auto-Injectors or any other Mylan Specialty products.

"Starting in the fall of 2012, all Chicago Public Schools (CPS) have undesignated epinephrine auto-injectors, provided through the EpiPen4Schools program. To date, we have already had several events in Chicago schools requiring the use of these EpiPen Auto-Injectors.¹ If symptoms of anaphylaxis are identified, a person should be treated with an epinephrine auto-injector and seek immediate emergency medical care after use,⁴" said Ruchi Gupta, M.D., M.P.H., Associate Professor of Pediatrics at Northwestern University and Lurie Children's Hospital. "As we work with CPS to help facilitate the anaphylaxis policies CPS has implemented, we are pleased to see them having the intended effect."

Important Safety Information (cont'd)

Tell your doctor if you have certain medical conditions such as asthma, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure and heart disease, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your doctor all the medicines you take, especially medicines for asthma. **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 take the EpiPen or EpiPen Jr Auto Injector.**

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness or anxiety. These side effects usually go away quickly, especially if you rest.

Talk to your healthcare professional to see if EpiPen or EpiPen Jr Auto-Injector is right for you.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information and Patient Information.

References: 1. Data on file. 2. Lieberman P, Nicklas RA, Oppenheimer J, et al. The diagnosis and management of anaphylaxis practice parameter: 2010 Update. *J Allergy Clin Immunol.* 2010;126(3):477-480.e1-e42. 3. Munoz-Furlong A, Weiss C, et al. Characteristics of food-allergic patients placing them at risk for a fatal anaphylactic episode. *Anaphylaxis and Drug Allergy.* 2009;9(1):57-63. 4. Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol.* 2011;126(6):S1-S58. 5. Sampson HA, Munoz-Furlong A, Campbell RL, et al. Second symposium on the definition and management of anaphylaxis: summary report-Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network Symposium. *J Allergy Clin Immunol.* 2006;117(2):391-397. 6. Simons FER. Anaphylaxis: recent advances in assessment and treatment *J Allergy Clin Immunol.* 2009; 635-636. 7. Sicherer SH, Simons F. Quandaries in prescribing an emergency action plan and self-injectable epinephrine for first-aid management of anaphylaxis in the community. *J Allergy Clin Immunol.* 2005; 116(3): 575-583. 8. McIntyre C, Sheetz A, et al. Administration of epinephrine for life-threatening allergic reactions in school settings. *Pediatrics.* 2005; 116(5): 1134-1140.

EPIPEN 2-PAK® [EpiPen 2-PAK®]

(Epinephrine) Auto-Injectors 0.3/0.15mg



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epipen.com

PRESCRIBING INFORMATION

EPIPEN®

(epinephrine) Auto-Injector 0.3 mg

EpiPen® = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 ml)

EPIPEN JR®

(epinephrine) Auto-Injector 0.15 mg

EpiPen Jr® = one dose of 0.15 mg epinephrine (USP, 1:2000, 0.3 mL)

DESCRIPTION

Each EpiPen® Auto-Injector delivers a **single dose** of 0.3 mg epinephrine injection, USP, 1:1000 (0.3 ml) in a sterile solution.

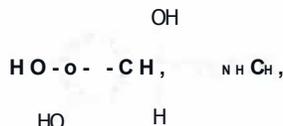
Each EpiPen Jr® Auto-Injector delivers a **single dose** of 0.15 mg epinephrine injection, USP, 1:2000 (0.3 ml) in a sterile solution.

The EpiPen Auto-Injector and EpiPen Jr Auto-Injector (henceforth referred to as EpiPen and EpiPen Jr Auto-Injector) each contain 2 ml epinephrine solution. Approximately 1.7 ml remains in the auto-injector after activation and cannot be used.

Each 0.3 ml in the EpiPen Auto-Injector contains 0.3 mg epinephrine, 18 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Each 0.3 ml in the EpiPen Jr Auto-Injector contains 0.15 mg epinephrine, 18 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is B-(3, 4-dihydroxyphenyl)- α -methyl-aminoethanol, with the following structure:



Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Replace EpiPen and EpiPen Jr Auto-Injectors if the epinephrine solution appears discolored.

EpiPen and EpiPen Jr Auto-Injectors do not contain latex.

CLINICAL PHARMACOLOGY

Epinephrine is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to insect stings or bites, foods, drugs, and other allergens. It can also be used in the treatment of anaphylaxis of unknown cause (idiopathic anaphylaxis) or exercise-induced anaphylaxis. When given intramuscularly or subcutaneously it has a rapid onset and short duration of action. Epinephrine acts on both alpha and beta adrenergic receptors. Through its action on alpha adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension. Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation that helps alleviate bronchospasm, wheezing and dyspnea that may occur during anaphylaxis. Epinephrine also alleviates pruritus, urticaria, and angioedema and may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxer effects on the smooth muscle of the stomach, intestine, uterus, and urinary bladder.

INDICATIONS AND USAGE

EpiPen and EpiPen Jr Auto-Injectors are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitos), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiopaque media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. EpiPen and EpiPen Jr Auto-Injectors are intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight (see **DOSAGE AND ADMINISTRATION** section).

Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

EpiPen and EpiPen Jr Auto-Injectors are intended for immediate self-administration as emergency supportive therapy only and are not a substitute for immediate medical care.

CONTRAINDICATIONS

There are no absolute contraindications to the use of epinephrine in a life-threatening situation.

WARNINGS

EpiPen and EpiPen Jr Auto-Injectors should **only** be injected into the anterolateral aspect of the thigh. **DO NOT INJECT INTO BUTTOCK.** Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis.

Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Treatment should be directed at vasodilation in addition to further treatment of anaphylaxis (see **ADVERSE REACTIONS**). Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection.

DO NOT INJECT INTRAVENOUSLY. Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

Epinephrine should be administered with caution in patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or

hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. It should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation.

Epinephrine is light sensitive and should be stored in the carrier tube provided. Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° C-30° C (59° F-86° F) (See USP Controlled Room Temperature). Do not refrigerate. Protect from light. Before using, check to make sure the solution in the auto-injector is not discolored. Replace the auto-injector if the solution is discolored or contains a precipitate.

PRECAUTIONS

(1) General

EpiPen and EpiPen Jr Auto-Injectors are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision.

Epinephrine is essential for the treatment of anaphylaxis. Patients with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens as well as idiopathic and exercise-induced anaphylaxis should be carefully instructed about the circumstances under which epinephrine should be used. It must be clearly determined that the patient is at risk of future anaphylaxis, since the following risks may be associated with epinephrine administration (see **DOSAGE and ADMINISTRATION**).

Epinephrine should be used with caution in patients who have cardiac arrhythmias, coronary artery or organic heart disease, hypertension, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, quinidine, or other anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias.

The effects of epinephrine may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include: hyperthyroid individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, pediatric patients under 30 kg (66 lbs.) body weight using EpiPen Auto-Injector, and pediatric patients under 15 kg (33 lbs.) body weight using EpiPen Jr Auto-Injector.

Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen or EpiPen Jr Auto-Injector to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which epinephrine should be used.

(2) Information for Patients

Complete patient information, including dosage, direction for proper administration and precautions can be found inside each EpiPen/EpiPen Jr Auto-Injector carton.

(Continued on back)

Epinephrine may produce symptoms and signs that include an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These symptoms and signs usually subside rapidly, especially with rest, quiet and recumbency. Patients with hypertension or hyperthyroidism may develop more severe or persistent effects, and patients with coronary artery disease could experience angina. Patients with diabetes may develop increased blood glucose levels following epinephrine administration. Patients with Parkinson's disease may notice a temporary worsening of symptoms.

In case of accidental injection, the patient should be advised to immediately go to the emergency room for treatment. Since the epinephrine in the EpiPen Auto-Injector is a strong vasoconstrictor when injected into the digits, hands or feet, treatment should be directed at vasodilation if there is such an inadvertent administration to these areas (see **ADVERSE REACTIONS**).

The carrier tube is not waterproof.

The blue safety release helps prevent accidental injection and should be kept on until it will be used.

(3) Drug Interactions

Patients who receive epinephrine while concomitantly taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines, notably chlorpheniramine, triprolidine and diphenhydramine.

The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol. The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine. Ergot alkaloids may also reverse the pressor effects of epinephrine.

(4) Carcinogenesis, Mutagenesis, Impairment of Fertility

Epinephrine and other catecholamines have been shown to have mutagenic potential *in vitro* and to be an oxidative mutagen in a *WP2* bacterial reverse mutation assay. Epinephrine had a moderate degree of mutagenicity, and was positive in the DNA Repair test with *S. subtilis* (REC) assay, but was not mutagenic in the *Salmonella* bacterial reverse mutation assay.

Studies of epinephrine after repeated exposure in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted. This should not prevent the use of epinephrine under the conditions noted under **INDICATIONS AND USAGE**.

(5) Usage in Pregnancy

Pregnancy Category C. There is no study on the acute effect of epinephrine on pregnancy. Epinephrine has been shown to have developmental effects when administered subcutaneously in rabbits at a dose of 1.2 mg/kg daily for two to three days (approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis), in mice at a subcutaneous dose of 1 mg/kg daily for 10 days (approximately 7 times the maximum daily subcutaneous or intramuscular dose on a mg/m² basis) and in hamsters at a subcutaneous dose of 0.5 mg/kg daily for 4 days (approximately 5 times the maximum

recommended daily subcutaneous or intramuscular dose on a mg/m² basis). These effects were not seen in mice at a subcutaneous dose of 0.5 mg/kg daily for 10 days (approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis). Although, there are no adequate and well-controlled studies in pregnant women, epinephrine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known if epinephrine passes into breast milk.

ADVERSE REACTIONS

Adverse reactions to epinephrine include transient, moderate anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or certain drugs (see **PRECAUTIONS, Drug Interactions**). Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease. The potential for epinephrine to produce these types of adverse reactions does not contraindicate its use in an acute life-threatening allergic reaction.

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area (see **WARNINGS**). Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoaesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury.

OVERDOSAGE

Epinephrine is rapidly inactivated in the body and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be counteracted by rapidly acting vasodilators or alpha-adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug.

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients.

Overdosage may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Treatment consists of a rapidly acting alpha-adrenergic blocking drug and/or respiratory support.

Epinephrine overdosage can also cause transient bradycardia followed by tachycardia and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of arrhythmias consists of administration of a beta-blocking drug such as propranolol.

Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis and kidney failure. Suitable corrective measures must be taken in such situations.

DOSAGE AND ADMINISTRATION

EpiPen or EpiPen Jr Auto-Injector prescribers should ensure that the patient or caregiver understands the indications and use of this product. A healthcare provider should review the patient instructions and operation of the EpiPen or EpiPen Jr Auto-Injector, in detail, with the patient or caregiver. Inject EpiPen or EpiPen Jr intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. See detailed Directions for Use on the accompanying Patient Instructions.

Selection of the appropriate dosage strength is determined according to patient body weight.

EpiPen Auto-Injector delivers 0.3 mg epinephrine injection (0.3 ml, 1:1000) and is intended for patients who weigh 30 kg or more (approximately 66 pounds or more).

EpiPen Jr Auto-Injector delivers 0.15 mg epinephrine injection (0.3 ml, 1:2000) and is intended for patients who weigh 15 to 30 kg (33 - 66 pounds).

Each EpiPen or EpiPen Jr Auto-Injector contains a single dose of epinephrine. Since the doses of epinephrine delivered from EpiPen or EpiPen Jr Auto-Injector are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary. The prescriber should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is indicated. With severe persistent anaphylaxis, repeat injections with an additional EpiPen Auto-Injector may be necessary.

Patients should be instructed to periodically visually inspect the epinephrine solution for particulate matter and discoloration. If the solution contains particulate matter or develops a pinkish or brown color, the patient should immediately contact their physician for a replacement, since these changes indicate that the effectiveness of the drug product may be decreased.

HOW SUPPLIED

EpiPen Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 ml) are available in individual cartons, NDC 49502-500-01, and as EpiPen 2-Pak®, NDC 49502-500-02, a pack that contains two EpiPen Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 ml) and one EpiPen Auto-Injector trainer device.

EpiPen Jr Auto-Injectors (epinephrine injection, USP, 1:2000, 0.3 ml) are available in individual cartons, NDC 49502-501-01, and as EpiPen Jr 2-Pak®, NDC 49502-501-02, a pack that contains two EpiPen Jr Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 ml) and one EpiPen Auto-Injector trainer device.

EpiPen 2-Pak® and EpiPen Jr 2-Pak® also includes an S-clip to clip two cases together.

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° C-30° C (59° F-86° F) (See USP Controlled Room Temperature). Do not refrigerate. Protect from light. Contains no latex.

Rx only.

MANUFACTURED FOR Mylan Specialty L.P., Basking Ridge, NJ 07920, USA by Meridian Medical Technologies, Inc., Columbia, MD 21046, USA, a Pfizer company

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PATIENT INFORMATION

EPIPEN®

(epinephrine) Auto-Injector 0.3 mg

EpiPen® • one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 ml)

EPIPEN JR®

(epinephrine) Auto-Injector 0.15 mg

EpiPen Jr® • one dose of 0.15 mg epinephrine (USP, 1:2000, 0.3 ml)

For allergic emergencies (anaphylaxis)

Read this Patient Information Leaflet carefully before using the EpiPen® Auto-Injector or EpiPen Jr® Auto-Injector (henceforth referred to as EpiPen or EpiPen Jr Auto-Injector), and each time you get a refill. There may be new information. You should know how to use the EpiPen or EpiPen Jr Auto-Injector 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 the EpiPen and EpiPen Jr Auto-Injector?

1. EpiPen and EpiPen Jr Auto-Injectors contain 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)
- dizziness, fainting, or "passing out" (unconsciousness)

2. Always carry your EpiPen or EpiPen Jr Auto-Injector with you because you may not know when anaphylaxis may happen.

Talk to your healthcare provider if you need additional units to keep at work, school, or other locations. Tell your family members and others where you keep your EpiPen or EpiPen Jr Auto-Injector and how to use it before you need it. You may be unable to speak in an allergic emergency.

3. When you have an allergic emergency (anaphylaxis) use the EpiPen

or EpiPen Jr Auto-Injector right away. Get emergency medical help right away.

You may need further medical attention. You may need a second EpiPen or EpiPen Jr Auto-Injector should symptoms persist or recur. More than two sequential doses of epinephrine for a single episode should only be administered by a healthcare provider.

What are the EpiPen and EpiPen Jr Auto-Injectors?

- EpiPen and EpiPen Jr Auto-Injector are disposable, prefilled automatic injection devices used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. They contain a single dose of epinephrine.
- EpiPen and EpiPen Jr Auto-Injector are for immediate self (or caregiver) administration and do not take the place of emergency medical care. You should get emergency help right away after using the EpiPen and EpiPen Jr Auto-Injector.
- EpiPen and EpiPen Jr Auto-Injector are for people who have been prescribed this medication by their healthcare provider.
- The EpiPen Auto-Injector (0.3 mg) is for patients who weigh 66 pounds or more (30 kilograms or more).
- The EpiPen Jr Auto-Injector (0.15 mg) is for patients who weigh about 33 to 66 pounds (15 to 30 kilograms).
- It is not known if EpiPen and EpiPen Jr Auto-Injectors are safe and effective in children who weigh less than 33 pounds (15 kilograms).

What should I tell my healthcare provider before using the EpiPen or EpiPen Jr Auto-Injector?

Before you use EpiPen or EpiPen Jr Auto-Injector, tell your healthcare provider about all your medical conditions, but especially if you:

- have heart problems or high blood pressure
- have diabetes
- have thyroid conditions
- have asthma
- have a history of depression
- have Parkinson's disease
- have any other medical conditions
- 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 non-prescription medicines, vitamins, and herbal supplements. Inform your healthcare provider of all known allergies.

Especially tell your healthcare provider if you take certain asthma medications,

EpiPen or EpiPen Jr Auto-Injector and other medicines may affect each other, causing side effects. EpiPen or EpiPen Jr Auto-Injector may affect the way other medicines work, and other medicines may affect how the EpiPen or EpiPen Jr Auto-Injector 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 EpiPen or EpiPen Jr Auto-Injector for treatment of anaphylaxis as prescribed by your healthcare provider, regardless of medical conditions or medication.

How should I use the EpiPen and EpiPen Jr Auto-Injector?

- Each EpiPen or EpiPen Jr Auto-Injector contains only 1 dose of medicine.
- The EpiPen or EpiPen Jr Auto-Injector should be injected into the muscle of your outer thigh. 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 EpiPen and EpiPen Jr Auto-Injector.
- Use your EpiPen or EpiPen Jr Auto-Injector exactly as your healthcare provider tells you to use it.
- **Caution: Never put your thumb, fingers, or hand over the orange tip. Never press or push the orange tip with your thumb, fingers, or hand.** The needle comes out of the orange tip. Accidental injection into finger, hands or feet may cause a loss of blood flow to these areas. **If this occurs, go immediately to the nearest emergency room.** Tell the healthcare provider where or your body you received the accidental injection.

- Your EpiPen and EpiPen Jr Auto-Injector may come packaged with an EpiPen Auto-Injector Trainer and separate Trainer Instructions for Use. **The EpiPen Auto-Injector Trainer has a grey color. The grey EpiPen Auto-Injector Trainer contains no medicine and no needle.** Practice with your EpiPen Auto-Injector Trainer before an allergic emergency happens to make sure you are able to safely use the real EpiPen and EpiPen Jr Auto-Injector in an emergency. Always carry your real EpiPen or EpiPen Jr Auto-Injector with you in case of an allergic emergency. Additional training resources are available at www.epipen.com.
- Do not drop the carrier tube or auto-injector. If the carrier tube or auto-injector is dropped, check for damage and leakage. Discard the auto-injector and carrier tube, and replace if damage or leakage is noticed or suspected.

What are the possible side effects of the EpiPen and EpiPen Jr Auto-Injector?

EpiPen and EpiPen Jr Auto-Injector may cause serious side effects.

The EpiPen or EpiPen Jr Auto-Injector should only be injected into the middle of your outer thigh (upper leg). Do not inject the EpiPen or EpiPen Jr Auto-Injector into your:

- vein
- buttock
- fingers, toes, hands, or feet

If you accidentally inject EpiPen or EpiPen Jr Auto-Injector into any other part of your body, go immediately to the nearest emergency room. Tell the healthcare provider where on your body you received the accidental 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 take the EpiPen or EpiPen Jr Auto-Injector. Talk to your healthcare provider about all your medical conditions.

Common side effects of the EpiPen and EpiPen Jr Auto-Injector include:

- fast, irregular or "pounding" heartbeat
- sweating
- headache
- weakness or shakiness
- paleness
- feelings of over excitement, nervousness or anxiety
- dizziness
- nausea and/or 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 the EpiPen or EpiPen Jr Auto-Injector. For more information, ask your healthcare provider or pharmacist.

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

How should I store the EpiPen and EpiPen Jr Auto-Injector?

- Store at 68° to 77° F (20° 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 contents in the clear window of your auto-injector periodically. The solution should be clear. If the solution is discolored (pinkish or brown color) or contains solid particles, replace the unit.
- Always keep your EpiPen or EpiPen Jr Auto-Injector in the carrier tube to protect it from damage; however, the carrier tube is not waterproof.
- The blue safety release helps to prevent accidental injection of the device. Keep the blue safety release on until you need to use it.
- Your EpiPen or EpiPen Jr Auto-Injector has an expiration date. Replace it before the expiration date.

General information about the safe and effective use of the EpiPen and EpiPen Jr Auto-Injector:

Do not use the EpiPen or EpiPen Jr Auto-Injector for a condition for which it was not prescribed. Do not give your EpiPen or EpiPen Jr Auto-Injector to other people.

This Patient Information Leaflet summarizes the most important information about the EpiPen and EpiPen Jr Auto-Injectors. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about the EpiPen and EpiPen Jr Auto-Injector that is written for health professionals.

For more information and video instructions on the use of the EpiPen and EpiPen Jr Auto-Injector, go to www.epipen.com or call 1-800-395-3376.

What are the ingredients in EpiPen and EpiPen Jr Auto-Injector?

Active Ingredients: Epinephrine

Inactive Ingredients: sodium chloride, sodium metabisulfite, hydrochloric acid, and water. The EpiPen and EpiPen Jr Auto-Injector contain **no latex**.

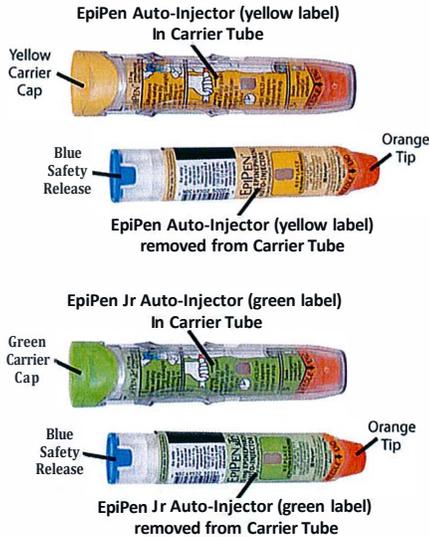
Important Information

- **The EpiPen Auto-Injector has a yellow colored label.**
- **The EpiPen Jr Auto-Injector has a green colored label.**
- **The EpiPen Trainer has a grey color, and contains no medicine and no needle.**
- **Your auto-injector is designed to work through clothing.**
- **The blue safety release on the EpiPen and EpiPen Jr Auto-Injector helps to prevent accidental injection of the device. Keep the blue safety release on until you need to use it.**
- **Only inject into outer thigh. Never inject into any other part of the body.**
- **Never put your thumb, fingers, or your hand over the orange tip. The needle comes out of the orange tip.**
- **If an accidental injection happens, get medical help right away.**
- **Do not place patient information or any other foreign objects in carrier with Auto-Injector, as this may prevent you from removing the Auto-Injector for use.**

Instructions for Use

Carefully read these Instructions for Use before you need to use your EpiPen or EpiPen Jr Auto-Injector. Before you use your EpiPen or EpiPen Jr Auto-Injector, make sure your healthcare provider shows you the right way to use it. If you have any questions, ask your healthcare provider.

Your EpiPen and EpiPen Jr Auto-Injector



3-Step Easy To Follow Instructions:

1. **Prepare** the EpiPen or EpiPen Jr Auto-Injector For Injection
 2. **Administer** the EpiPen or EpiPen Jr Auto-Injector
 3. **Finalize** the Injection Process
- (See detailed instructions below)

1. **Prepare** the EpiPen or EpiPen Jr Auto-Injector For Injection

Remove the auto-injector from the clear carrier tube.



Flip open the yellow cap of your EpiPen or the green cap of your EpiPen Jr Auto-Injector carrier tube.



Tip and slide the auto-injector out of the carrier tube.



Grasp the auto-injector in your fist with the orange tip pointing downward.

With your other hand, **remove the blue safety release by pulling straight up without bending or twisting it.**

Note:

- The needle comes out of the orange tip.
 - Never put your thumb, fingers or hand over the orange tip.
2. **Administer** the EpiPen or EpiPen Jr Auto-Injector

Hold the auto-injector with orange tip near the outer thigh.



Swing and firmly push the orange tip against the outer thigh until it 'clicks'. Keep the auto-injector firmly pushed against the thigh at a 90° angle (perpendicular) to the thigh.



Hold firmly against the thigh for approximately 10 seconds to deliver the drug. The injection is now complete.

3. **Finalize** the Injection Process



Remove the auto-injector from the thigh. The orange tip will extend to cover the needle.



Massage the injection area for 10 seconds.

Get emergency medical help right away. You may need further medical attention. You may need a second EpiPen or EpiPen Jr Auto-Injector should symptoms persist or recur.

Note:

- Take your used auto-injector with you when you go to see the healthcare provider.
- Tell the healthcare provider that you have received an injection of epinephrine. Show the healthcare provider where you received the injection.
- Give your used EpiPen or EpiPen Jr Auto-Injector to a healthcare provider for inspection and proper disposal.
- Ask for a refill, if needed.
- The used auto-injector with extended needle cover will not fit in the carrier tube.
- Most of the liquid medicine stays in the auto-injector and cannot be reused. You have received the correct dose of the medicine if the orange needle tip is extended and the window is blocked.
- Your EpiPen and EpiPen Jr Auto-Injector may come packaged with an EpiPen Auto-Injector Trainer and separate Trainer Instructions for Use. **The EpiPen Trainer**

has a grey color. The grey EpiPen Trainer contains no medicine and no needle. Practice with your EpiPen Trainer, but always carry your real EpiPen or EpiPen Jr Auto-Injector in case of an allergic emergency.

- Do not attempt to take the EpiPen or EpiPen Jr Auto-Injector apart.

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

Manufactured for:
Mylan Specialty L.P., Basking Ridge, NJ 07920, USA
by Meridian Medical Technologies, Inc.,
Columbia, MD 21046, USA, a Pfizer company

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Register your EpiPen or EpiPen Jr Auto-Injector at **MyEpiPen.com** and find out more about:

- Free EpiPen Auto-Injector **Refill Reminder Program.** It is important to keep your auto-injector up-to-date.
Register up to 6 EpiPen or EpiPen Jr Auto-Injectors and receive automatic **Refill Reminder Alerts.**
- Receive periodic information related to allergies and allergens.
- Instructional Video

For more information about EpiPen or EpiPen Jr Auto-Injectors and proper use of the product, visit www.epipen.com.

**CERTIFICATION FORM:
Free EpiPen® (epinephrine injection) Auto-Injector EpiPen4Schools®
Program**

The school and/or school district identified below (the "School") hereby acknowledges and agrees that the Free EpiPen® (epinephrine injection) Auto-Injector EpiPen4Schools® Program made available by Mylan Specialty L.P. ("Mylan Specialty") to the School is because it is a school and is conditioned upon the undersigned making this certification to Mylan Specialty.

The School represents and warrants to Mylan Specialty that:

- (i) all of the information provided in this certification is true, complete and accurate;
- (ii) the School will only receive EpiPen® (epinephrine injection) 0.3mg and EpiPen Jr® (epinephrine injection) 0.15mg Auto-Injectors in accordance with all applicable laws for use by the School, and the School has presented a valid prescription for the product;
- (iii) the School is an entity whose primary purpose is education for students in grades K through 12 that is licensed as an educational facility under all applicable laws;
- (iv) the School shall make best efforts to provide appropriate product training to any School personnel who may administer an EpiPen or EpiPen Jr Auto-Injector;
- (v) the person signing this certification on behalf of the School has the requisite authority to make this certification on behalf of the School identified below;
- (vi) such EpiPen® Auto-Injectors received by the School shall be for its own use and the School shall not sell or transfer any such EpiPen® Auto-Injectors received pursuant to the Free EpiPen® Auto-Injector EpiPen4Schools Program to a non-school third party, unless the prior written approval of Mylan Specialty, in its sole discretion, is obtained;
- (vii) any transfer of any quantity of EpiPen® Auto-Injectors received pursuant to the Free EpiPen® Auto-Injector EpiPen4Schools Program available to schools in violation of this certification will be considered a breach of this certification allowing Mylan Specialty to prohibit the School from receiving EpiPen® Auto-Injectors pursuant to the Free EpiPen® Auto-Injector EpiPen4Schools Program available to schools;
- (viii) neither the School, nor any healthcare professional associated with or providing medical services on behalf of the School, will bill any patient or any third-party payer/government program for any free EpiPen® or EpiPen Jr® Auto-Injector administered to any patient; and
- (ix) the School agrees to Mylan Specialty's use of the School's name for promotional purposes.

Please input the number of EpiPen 2-Pak® and/or EpiPen Jr 2-Pak® cartons below.

Authorized Schools are eligible to receive four EpiPen® Auto-Injectors in the form of two EpiPen 2-Pak® cartons; or two EpiPen Jr 2-Pak® cartons; or one of each 2-Pak cartons. Total quantity ordered must be no more than two 2-Pak cartons.

Two FREE 2-Pak Cartons (4 Total EpiPen® Auto-Injectors)	Quantity Ordered*	Price
EpiPen 2-Pak™ Cartons		FREE
EpiPen Jr 2-Pak™ Cartons		FREE
Total Quantity Ordered (*must be no more than two 2-Pak		FREE
Epilocker™ (limit one per school)		FREE

Please check if you would like to receive periodic updates about this program or EpiPen® Auto-Injector.

**Please note there are two auto-injectors per EpiPen 2-Pak® or EpiPen Jr 2-Pak®. Example: If you wish to order 2 EpiPen® Auto-Injectors and 2 EpiPen Jr® Auto-Injectors, put the number 1 in the Quantity Ordered box next to EpiPen 2-Pak® and 1 in the Quantity Ordered box next to EpiPen Jr 2-Pak®. If you wish to order 4 EpiPen Jr® Auto-Injectors, put the number 2 in the Quantity Ordered box next to EpiPen Jr 2-Pak and 0 (zero) in the Quantity Ordered box next to EpiPen 2-Pak®.*

† ORDERING FOR MULTIPLE SCHOOLS: *If you are ordering for multiple schools within a single school district, you may order up to two 2-Pak cartons per school. For example, if you are ordering two EpiPen Jr 2-Pak® cartons for each of 10 schools, you should enter 20 in the Quantity Ordered column next to EpiPen Jr 2-Pak® cartons. Under this scenario, your total quantity ordered cannot exceed the number of schools multiplied by 2*

If the terms and conditions provided in this certification are amended, modified or altered in any way, it will be considered null and void.

School/School District Name:	
School Address:	
City/State/Zip:	
School Phone:	
Authorized School Signatory Name:	
Authorized School Signatory Title:	
Authorized School Signatory Email:	
Signature:	I Date:

Please fax the completed Certification Form and a copy of a valid EpiPen® Auto-Injector prescription to BioRidge Pharma, LLC
Attn: Kristina Paich Fax: 973-718-4328 or email scan to: info@bioridgepharma.com
Phone: 973-845-7600

Indications

EpiPen® (epinephrine injection) 0.3 mg and EpiPen Jr® (epinephrine injection) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen® and EpiPen Jr® are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

Important Safety Information

EpiPen® and EpiPen Jr® Auto-Injectors contain a single dose of epinephrine, which you (or your caregiver or others who may be in a position to administer EpiPen® or EpiPen Jr®) inject into the middle of your outer thigh (upper leg) (through clothing, if necessary). Get emergency medical help right away. You may need further medical attention. Only a health care professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. **DO NOT INJECT INTO YOUR VEINS, BUTTOCKS, FINGERS, TOES, HANDS OR FEET.** In case of accidental injection, please seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Tell your doctor if you have certain medical conditions such as asthma, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure or heart disease, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your doctor all the medicines you take, especially medicines for asthma. **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 EpiPen® or EpiPen Jr®.**

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea or vomiting, difficulty breathing, paleness, dizziness, weakness, shakiness, headache, apprehension, nervousness or anxiety. These side effects may go away if you rest. **Tell your health care professional if you have any side effect that bothers you or that does not go away.**

Please see the full [Prescribing Information and Patient Information](#).

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional information, please contact us at 800-395-3376.

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CERTIFICATION FORM: EpiPen4Schools® Replenishment Offer

Mylan Specialty will replenish your school's supply of EpiPen® (epinephrine injection) or EpiPen Jr® (epinephrine injection) Auto-Injectors prior to your annual eligibility date and at no additional cost, provided that your school used the EpiPen4Schools® free product to treat a life-threatening allergic reaction (anaphylaxis) in your school.

First, please complete all of the fields below.

School Name/District Name:
School Address:
City/State/Zip:
School Phone:
School Contact Name:
School Contact Email:
What was the date of the anaphylactic event? MM/DD/YYYY
Where did the anaphylactic event occur? <ul style="list-style-type: none"> • Class room • Cafeteria • Playground • Gym • Other
What was the suspected cause of the anaphylactic event? <ul style="list-style-type: none"> • Food • Bee sting • Latex • Medication • Other
Did the person who experienced anaphylaxis have a known life-threatening allergy? <ul style="list-style-type: none"> • Yes • No
Was the person who experienced anaphylaxis a <ul style="list-style-type: none"> • Student • Staff member • Visitor • Other
Was an EpiPen® or EpiPen Jr® Auto-Injector administered to treat the anaphylactic event? <ul style="list-style-type: none"> • EpiPen® Auto-Injector • EpiPen Jr® Auto-Injector
Was more than one EpiPen™ or EpiPen Jr® Auto-Injector administered to treat the anaphylactic event? <ul style="list-style-type: none"> • Yes • No
Who administered the EpiPen™ or EpiPen Jr® Auto-Injector to the person experiencing anaphylaxis (please do not name people directly)? <ul style="list-style-type: none"> • School Nurse • Student • Staff member • Visitor
Was 911 called? <ul style="list-style-type: none"> • Yes • No
Did the person who experienced anaphylaxis receive emergency medical care? <ul style="list-style-type: none"> • Yes • No
Was the person who experienced anaphylaxis taken to the hospital? <ul style="list-style-type: none"> • Yes

CERTIFICATION FORM:
***EpiPen4 Schools*[®] Replenishment Offer**

<ul style="list-style-type: none">• No
How were the EpiPen [®] or EpiPen Jr [®] Auto-Injectors disposed?
If school policies permit, would you be willing to speak with us about the event? <ul style="list-style-type: none">• Yes• No

D I confirm that the EpiPen[®] or EpiPen Jr[®] Auto-Injector used in the anaphylactic event described above was received through the *EpiPen4Schools* program.

D I certify that the information above is true and accurate.

Signature:

Date:

Indications

EpiPen[®] (epinephrine injection) 0.3 mg and EpiPen Jr[®] (epinephrine injection) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen[®] and EpiPen Jr[®] are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

Important Safety Information

EpiPen[®] and EpiPen Jr[®] Auto-Injectors contain a single dose of epinephrine, which you (or your caregiver or others who may be in a position to administer EpiPen[®] or EpiPen Jr[®]) inject into the middle of your outer thigh (upper leg) (through clothing, if necessary). Get emergency medical help right away. You may need further medical attention. Only a health care professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. **DO NOT INJECT INTO YOUR VEINS, BUTTOCKS, FINGERS, TOES, HANDS OR FEET.** In case of accidental injection, please seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Tell your doctor if you have certain medical conditions such as asthma, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure or heart disease, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your doctor all the medicines you take, especially medicines for asthma. **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 EpiPen[®] or EpiPen Jr[®].**

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea or vomiting, difficulty breathing, paleness, dizziness, weakness, shakiness, headache, apprehension, nervousness or anxiety. These side effects may go away if you rest. **Tell your health care professional if you have any side effect that bothers you or that does not go away.**

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