



**Subject:** Sue Buswell color copies

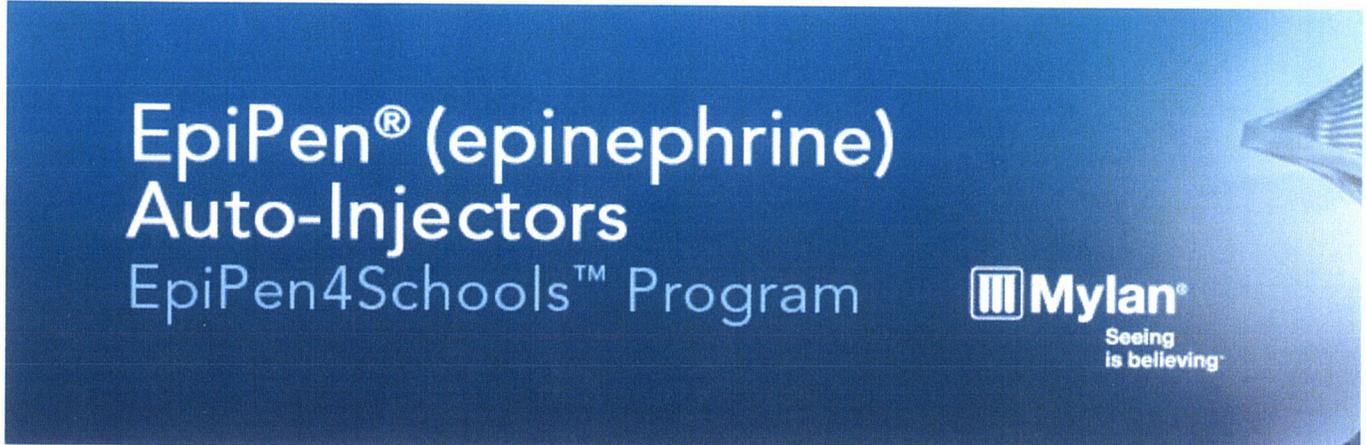
**Date:** Friday, January 25, 2013 10:09:58 AM MT (CA)

**From:** Buswell <wheeze@mt.net>

**To:** gina@allegrahelena.com <gina@allegrahelena.com>, Gina@allegrahelena.com <Gina@allegrahelena.com>

PROGRAMS

CONTACT BIORIDGE PHARMA



Welcome to the EpiPen® (epinephrine) Auto-Injectors EpiPen4Schools™ Program, offered by Mylan Specialty L.P., the distributor and marketer of EpiPen® (epinephrine) 0.3mg and EpiPen Jr® (epinephrine) 0.15mg Auto-Injectors.

The EpiPen4Schools program was created to allow qualified schools to obtain EpiPen Auto-Injectors at no-cost. This access is important because epinephrine is the only first-line treatment for life-threatening allergic reactions (anaphylaxis). According to food allergy guidelines developed by the National Institute of Allergy and Infectious Diseases, if experiencing anaphylaxis, a person should use an epinephrine auto-injector and seek immediate emergency medical attention. Carrying an epinephrine auto-injector does not prevent patients from having an anaphylactic reaction; hence, patients must remain vigilant of their environment at all times.

Each eligible school can receive up to four FREE EpiPen or EpiPen Jr Auto-Injectors in the form of two EpiPen 2-Pak® cartons, two EpiPen Jr 2-Pak® cartons, or one 2-Pak of each kind. Each EpiPen 2-Pak contains two single auto-injectors, instructions for use and a training device, with no drug product or needle, to help patients become familiar with the administration technique.

In addition to the EpiPen4Schools program, Mylan Specialty offers a discount program through which schools can purchase, upon qualification, EpiPen 2-Pak cartons (0.3 mg) and EpiPen Jr 2-Pak cartons (0.15 mg) at a discounted price of \$112.10 each.



**Indica**

EpiPen (epinephrine) Auto-Injectors are indicated for the treatment of severe allergic reactions (anaphylaxis) in patients with a known hypersensitivity to one or more allergens. EpiPen and EpiPen Jr are not for use in patients with known hypersensitivity to epinephrine or any of the other ingredients. See full prescribing information for complete details. See also the Important Information about EpiPen and EpiPen Jr on the adjacent page.

**Import**

EpiPen and EpiPen Jr are not for use in patients with known hypersensitivity to epinephrine or any of the other ingredients. See full prescribing information for complete details. See also the Important Information about EpiPen and EpiPen Jr on the adjacent page.

If you have a severe allergic reaction, use EpiPen or EpiPen Jr immediately. Do not delay. See full prescribing information for complete details. See also the Important Information about EpiPen and EpiPen Jr on the adjacent page.

# How to use EpiPen® and EpiPen® Jr Auto-injectors.

Remove EpiPen® Auto-injector from carrier tube

1



- Hold firmly with orange tip pointing downward
- Remove blue safety release

2



- Swing and push orange tip firmly into mid-outer thigh until you hear a 'click'
- Hold on thigh for several seconds



#### Built-in needle protection

- When the EpiPen® Auto-injector is removed, the orange needle cover automatically extends to cover the injection needle



*After administration, patients should seek medical attention immediately or go to the emergency room. For the next 48 hours, patients must stay within close proximity to a healthcare facility or where they can call 911.*

For more information go to [www.EpiPen.ca](http://www.EpiPen.ca)

EpiPen® and EpiPen® Jr Auto-injectors are indicated for the emergency treatment of anaphylactic reactions in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

This product may not be right for you. Always read and follow the product label.



© 2010 King Pharmaceuticals Canada, Inc.  
2915 Argenta Road, Suite 7, Mississauga, Ontario L5N 8G6  
Toll free: 1-877-EPIPEN1 (1-877-374-7361) • Tel: 1-905-812-9911 • Fax: 1-905-812-9916  
EpiPen® is a registered trademark of Mylan Inc. licensed exclusively to its wholly-owned subsidiary, Dey Pharma, L.P. of Napa, California, USA.  
EPI-09-115B



**Emergency response at hand.**

**CERTIFICATION FORM:  
Free EpiPen® Auto-Injector EpiPen4Schools™ Program**

The school and/or school district identified below (the "School") hereby acknowledges and agrees that the Free EpiPen® (epinephrine) 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) 0.3mg and EpiPen Jr® (epinephrine) 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; and
- (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.

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 E-mail:	
Signature:	Date:

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

Authorized Schools are eligible to receive four EpiPen Auto-Injectors in the form of two EpiPen 2-Pak units; or two EpiPen Jr 2-Pak units; or one of each 2-Pak units.

Total quantity ordered must be no more than two 2-Paks.

Two FREE 2-Pak Units (4 Total EpiPen Auto-Injectors)	Quantity Ordered*	Price
EpiPen 2-Pak® Units		FREE
EpiPen Jr 2-Pak® Units		FREE
Total Quantity Ordered (*must be no more than two 2-Pak Units)		FREE

*\*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.*

**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 e-mail scan to: info@bioridgepharma.com  
 Phone: 973-845-7600

# Food Allergy Action Plan

## Emergency Care Plan

Place  
Student's  
Picture  
Here

Name: \_\_\_\_\_ D.O.B.: \_\_\_\_/\_\_\_\_/\_\_\_\_

Allergy to: \_\_\_\_\_

Weight: \_\_\_\_\_ lbs. Asthma:  Yes (higher risk for a severe reaction)  No

Extremely reactive to the following foods: \_\_\_\_\_

### THEREFORE:

- If checked, give epinephrine immediately for ANY symptoms if the allergen was *likely* eaten.
- If checked, give epinephrine immediately if the allergen was *definitely* eaten, even if no symptoms are noted.

### Any SEVERE SYMPTOMS after suspected or known ingestion:

#### One or more of the following:

- LUNG: Short of breath, wheeze, repetitive cough
- HEART: Pale, blue, faint, weak pulse, dizzy, confused
- THROAT: Tight, hoarse, trouble breathing/swallowing
- MOUTH: Obstructive swelling (tongue and/or lips)
- SKIN: Many hives over body

#### Or combination of symptoms from different body areas:

- SKIN: Hives, itchy rashes, swelling (e.g., eyes, lips)
- GUT: Vomiting, diarrhea, crampy pain



### 1. INJECT EPINEPHRINE IMMEDIATELY

2. Call 911
3. Begin monitoring (see box below)
4. Give additional medications: \*
  - Antihistamine
  - Inhaler (bronchodilator) if asthma

\*Antihistamines & inhalers/bronchodilators are not to be depended upon to treat a severe reaction (anaphylaxis). USE EPINEPHRINE.

### MILD SYMPTOMS ONLY:

- MOUTH: Itchy mouth
- SKIN: A few hives around mouth/face, mild itch
- GUT: Mild nausea/discomfort



### 1. GIVE ANTIHISTAMINE

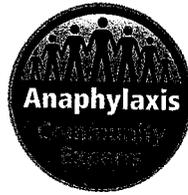
2. Stay with student; alert healthcare professionals and parent
3. If symptoms progress (see above), USE EPINEPHRINE
4. Begin monitoring (see box below)

### Medications/Doses

Epinephrine (brand and dose): \_\_\_\_\_

Antihistamine (brand and dose): \_\_\_\_\_

Other (e.g., inhaler-bronchodilator if asthmatic): \_\_\_\_\_



# ANAPHYLAXIS ACTION PLAN

Name \_\_\_\_\_

Age/DOB \_\_\_\_\_ / \_\_\_\_\_

History of asthma  Yes  No Allergies  Yes  No NOTE: "Yes" indicates increased risk factors.

Allergens known to trigger anaphylactic reactions for this person:

\_\_\_\_\_  
\_\_\_\_\_

Epinephrine auto-injector brand name and dose:

\_\_\_\_\_

NOTE: Epinephrine is always the FIRST medication given. Administer secondary medications if needed:

\_\_\_\_\_

Patient has been taught how and when to use this epinephrine auto-injector:  Yes  No

NOTE: Due to the nature of anaphylaxis, the patient may or may not be able to self-administer medication during a crisis.

**A**

**Act immediately:** Administer epinephrine auto-injector in thigh when:

\_\_\_\_\_

**C**

**Call for help:** 911/Rescue Squad.

Speak to at least one person on the emergency contact list below.

**E**

**Expect RAPID results:** IF NO IMPROVEMENT WITHIN 5 - 15 MINUTES, administer second epinephrine auto-injector dose.

## EMERGENCY CONTACT INFORMATION:

Name \_\_\_\_\_ Phone \_\_\_\_\_ Relationship \_\_\_\_\_

Name \_\_\_\_\_ Phone \_\_\_\_\_ Relationship \_\_\_\_\_

Name \_\_\_\_\_ Phone \_\_\_\_\_  
Relationship \_\_\_\_\_

Healthcare Provider Signature \_\_\_\_\_ Contact Number \_\_\_\_\_ Date \_\_\_\_\_

Patient or Parent/Guardian of minor child \_\_\_\_\_ Contact Number \_\_\_\_\_ Date \_\_\_\_\_

## Sample LHCP Letter Regarding Unlicensed Staff Administering Emergency Medication at School

Dear: \_\_\_\_\_

Date: \_\_\_\_\_

The new Washington State *Guidelines for Care of Students with Anaphylaxis* (2009) includes current best practice information from recognized national authorities regarding anaphylaxis and administering epinephrine (see attached). Based on the attached information, the guidelines provide the following recommendations for Washington schools:

1. If a student, known to have anaphylaxis, has an exposure or a suspected exposure to an allergen, epinephrine is to be given immediately and the EMS (911) system activated.
2. If a LHCP orders the administration of an antihistamine and/or epinephrine, the R.N. may use the Scope of Practice Decision Tree to follow RCW 18.79, to determine if a non-licensed staff member may carry out the emergency care plan (ECP).
3. Address the unique circumstances for each student while retaining adherence to the scope of nursing practice.

Given the attached information and the above recommendations, the emergency procedure for this student when experiencing possible anaphylaxis will be to:

- |   |
|---|
| <ol style="list-style-type: none"><li>1. Administer Epinephrine</li><li>2. Call 911</li><li>3. Call Parent/Guardian</li></ol> |
|---|

Additional contributing circumstances:

1. In most situations non-licensed school staff (health clerks, secretaries, principals, teachers, coaches, bus drivers, etc.) will be the front line adults on site when the student has a contact to the specific allergen causing potential anaphylaxis.
2. Upon consulting with NCQAC staff, it was determined "waiting and watching" could require a degree of assessment requiring judgment beyond a non-licensed individual.
3. For the safety of the student, epinephrine will be administered immediately as ordered by the health care provider.

Thank you for your assistance in implementing this requirement. Please contact me if you have any questions.

Sincerely,

\_\_\_\_\_  
School Nurse

\_\_\_\_\_  
Phone

Adapted with permission from ESD 105 SNC Program

The medical standard of care, written by AAAAI states, *"Epinephrine has long been regarded as the treatment of choice for acute anaphylaxis. This is true despite the recognition of its potential hazards. Alternative treatments - such as antihistamines, sublingual isoproterenol, inhaled epinephrine, and corticosteroids without epinephrine - have failed to prevent or relieve severe anaphylactic reactions. It is therefore inappropriate to use them for the first-line treatment or prevention of anaphylaxis."*

AAAAI Press Room, "Position Statement the Use of Epinephrine in the Treatment of Anaphylaxis." 2008, [http://www.aaaai.org/members/academy\\_statements/position\\_statements/ps26.asp](http://www.aaaai.org/members/academy_statements/position_statements/ps26.asp) accessed on October 30, 2008.

Additionally, in July 2008, the World Allergy Organization published the following statements,

Anaphylaxis is an acute and potentially lethal multisystem allergic reaction. Most consensus guidelines for the past 30 years have held that epinephrine is the drug of choice and the first drug that should be administered in acute anaphylaxis. Some state that properly administered epinephrine has no absolute contraindication in this clinical setting. A committee of anaphylaxis experts assembled by the World Allergy Organization has examined the evidence from the medical literature concerning the appropriate use of epinephrine for anaphylaxis. The committee strongly believes that epinephrine is currently underused and often dosed suboptimally to treat anaphylaxis, is underprescribed for potential future self-administration, that most of the reasons proposed to withhold its clinical use are flawed, and that the therapeutic benefits of epinephrine exceed the risk when given in appropriate intramuscular doses.

Based on available evidence, the benefit of using appropriate doses of intramuscular epinephrine in anaphylaxis far exceeds the risk.... Consensus opinion and anecdotal evidence recommend epinephrine administration sooner rather than later, that is, when the initial signs and symptoms of anaphylaxis occur, regardless of their severity, because fatalities in anaphylaxis usually result from delayed or inadequate administration of epinephrine. Experts may differ on how they define the clinical threshold by which they define and treat anaphylaxis. However, they have no disagreement whatsoever that appropriate doses of intramuscular epinephrine should be administered rapidly once that threshold is reached. There is no absolute contraindication to epinephrine administration in anaphylaxis, and all subsequent therapeutic interventions depend on the initial response to epinephrine.

AAAAI Board of Directors, "Position Statement Anaphylaxis in Schools and Other Child-Care Settings," 2008, [http://www.aaaai.org/media/resources/academy\\_statements/position\\_statements/ps34.asp](http://www.aaaai.org/media/resources/academy_statements/position_statements/ps34.asp), accessed on February 26, 2008.

## Sample Training Program

### Teaching Plan Objectives

#### The learner will:

1. Identify (name) \_\_\_\_\_'s allergies.
2. Identify the signs and symptoms of an allergic reaction and anaphylaxis.
3. Be able to initiate treatment for an allergic reaction and specifically carry out an emergency allergy treatment plan.
4. Demonstrate how to use the EpiPen® or EpiPen® Jr. effectively as a treatment for an allergic reaction and anaphylaxis.
5. Understand the potential for cross-contamination of identified allergens.
6. Be able to communicate to students, caregivers, and other staff information about allergies and precautions.
7. Understand how Section 504 applies to students with allergies.

#### Methods of Delivery and Time Frame

The learner will complete the pre-assessment prior to the initial training session. At the initial training session, (student's name)'s and allergies will be identified, allergy kit supplies identified and explained, emergency allergy treatment plan discussed, and use of EpiPen® Jr. demonstrated. The learner will demonstrate knowledge of (student's name)'s and allergies, knowledge of location of allergy supplies, and proper use of EpiPen® Jr. Any questions will also be answered. The Allergy Training Kit will be given to the learner and a follow-up training session will be scheduled.

Estimated time of initial training session: 20 minutes.

At the follow-up training session, the learner will demonstrate knowledge of (student's name)'s and allergies, knowledge of location of allergy supplies, and proper use of EpiPen® Jr. In addition, the learner will demonstrate knowledge of anaphylaxis, cross-contamination, and Section 504 as it applies to the student with allergies. Knowledge will be demonstrated through use of EpiPen Jr.® Trainer, discussion, and completion of both the training assessment and post-assessment. Estimated time frame: 20–30 minutes.

#### Instructional Media

The Allergy Training Kit is contained in a briefcase-like plastic case with a handle. It contains the following instructional media:

#### EpiPen® Jr. Trainer

This is a duplicate of the actual EpiPen® Jr. used to treat allergic reactions and anaphylaxis. It does not contain a needle or epinephrine, and can be reset and used repeatedly for instruction and demonstration.

### **Videos**

1. It Only Takes One Bite: Food Allergy and Anaphylaxis Video
2. Alexander, The Elephant Who Couldn't Eat Peanuts Video

### **Books**

1. Getting Started with Food Allergies: A Guide for Parents
2. Just One Little Bite Can Hurt! Important Facts About Anaphylaxis
3. Off to School with Food Allergies, Parent/Teacher Set
4. Students with Food Allergies: What Do the Laws Say?
5. Nutrition Guide to Food Allergies
6. A Special Day at School
7. Andrew and Maya Learn About Food Allergies
8. Food Allergy Network Ordering Brochure
9. Miss Roben's Catalog

### **Printed References**

This is a collection of physician's orders, articles, resources, and Web sites from various sources including newspapers, magazines, and the World Wide Web. The Emergency Allergy Treatment Plan individual health plan/emergency health plan (IHP/ECP) is written by the student's LHCP and updated yearly. It is the actual treatment orders to be given to personnel such as emergency medical technicians or emergency room staff. A copy of the IHP/ECP is also kept with the medical kit, which contains the EpiPen® Jr. and Benadryl®.