



## **Dey Pharma to Offer EpiPen 2-Pak® and EpiPen Jr 2-Pak® Exclusively**

### **Decision aligns with recent clinical guidelines for patients at risk for or who have experienced anaphylaxis to have immediate access to two doses of epinephrine(1)**

BASKING RIDGE, N.J., Aug. 24, 2011 /PRNewswire/ -- Dey Pharma, L.P., a subsidiary of Mylan Inc. (Nasdaq: MYL), today announced that Dey will exclusively offer the EpiPen 2-Pak® and EpiPen Jr 2-Pak® (epinephrine) Auto-Injector 0.3/0.15 mg, to encourage physicians and patients to follow recommendations by the National Institute of Allergy and Infectious Diseases (NIAID). While there is no safety issue with the EpiPen® and EpiPen Jr single package, Dey will transition away from distributing and marketing these configurations in the U.S.

The "Guidelines for the Diagnosis and Management of Food Allergy in the United States," which were developed by an expert panel sponsored by the NIAID, a division of the National Institutes of Health (NIH), recommend that patients at risk for or who have experienced anaphylaxis have immediate access to two doses of epinephrine.(1) More specifically, the guidelines indicate that if a patient responds poorly to the initial dose or has ongoing or progressive symptoms despite initial dosing, repeated dosing may be required after five to 15 minutes.(1) Patients should seek immediate emergency medical treatment after use of EpiPen or EpiPen Jr.

Mylan President Heather Bresch commented: "Many people may not be aware that recent food allergy guidelines state that patients at risk for or who have experienced anaphylaxis should have immediate access to two doses of epinephrine. The decision to exclusively offer the EpiPen 2-Pak, which contains two single EpiPen Auto-Injectors, aligns with these guidelines, as well as with the 2011 World Allergy Organization (WAO) anaphylaxis guidelines which recommend that physicians consider prescribing more than one epinephrine auto-injector.(2) Mylan and Dey are committed to increasing the overall awareness of being prepared for a potentially life-threatening allergic reaction."

Dr. Phillip Lieberman, Clinical Professor of Medicine and Pediatrics at University of Tennessee College of Medicine, and member of the NIAID-sponsored expert panel added: "The guidelines recognize that up to 20% of those who receive epinephrine will require more than one dose before symptoms are relieved. In addition, the need for additional epinephrine cannot be reliably predicted at the onset of a reaction.(4,5) Therefore, consistent with the guidelines, patients prescribed an epinephrine auto-injector should be given a prescription which allows two doses."

Each EpiPen 2-Pak contains an EpiPen Auto-Injector training device to help patients become comfortable with administration. The training device contains no drug product or needle.

Dey is no longer shipping single EpiPen Auto-Injector package configurations in the U.S.; however, the single EpiPen Auto-Injector may still be available at certain pharmacies for a few weeks until their stock is depleted. The single EpiPen Auto-Injector package configuration will continue to be available outside of the U.S.

If there are any questions regarding the transition away from single EpiPen Auto-Injectors, please contact Dey Customer Service at 800.395.3376.

### **About Anaphylaxis**

Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death,(3,4) either through swelling that shuts off airways or through a significant drop in blood pressure.(3,4) Anaphylaxis can be triggered by certain foods, insect stings, medications, latex or other allergens.(3) Food allergies, a medical condition which has recently been reported to affect one in 13 children in the U.S.,(6) are the most common trigger of anaphylaxis.(6)

### **About EpiPen Auto-Injector**

EpiPen® and EpiPen Jr (0.3 and 0.15 mg epinephrine) Auto-Injectors are for the emergency treatment of severe allergic reactions (anaphylaxis). As with any medication, EpiPen Auto-Injector has an expiration date printed directly on the side of the auto-injector and end side of the carton and should be replaced when the unit expires. The product should be stored at room temperature, protected from light and never refrigerated or kept where it might be exposed to extreme temperatures, such as in the glove compartment of a car.

Dey Pharma, L.P., the distributor of EpiPen Auto-Injector, offers patient support through a program that has a free membership at [www.myeipen.com](http://www.myeipen.com). This program provides helpful tips, resources and an expiration reminder program.

## Indications

EpiPen and EpiPen Jr (0.3 and 0.15 mg epinephrine) 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 INTRAVENOUSLY. DO NOT INJECT INTO YOUR BUTTOCK, as this may not be effective. 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.

**If you take certain medicines, you may develop serious life-threatening side effects from the epinephrine in EpiPen Auto-Injectors.** Be sure to tell your doctor all the medicines you take, especially medicines for asthma. Side effects may be increased in patients with certain medical conditions, or who take certain medicines. These include asthma, allergies, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure and heart disease.

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.

Please [click here](#) to view the EpiPen prescribing information.

Please [click here](#) for the EpiPen patient insert.

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

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

## About Dey

Dey Pharma, L.P., a subsidiary of Mylan Inc. (Nasdaq: MYL), is a specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drug products for the treatment of respiratory diseases, severe allergic reactions and psychiatric disorders. The company puts patients first and facilitates efficient, cost-effective partnerships with customers. For more information, please visit [www.dey.com](http://www.dey.com).

## About Mylan

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information, please visit [www.mylan.com](http://www.mylan.com).

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## References

1. 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*. 2010;126(6 suppl):S1-S58.
2. Simons FE, Arduzzo LR, Bilo MB, et al; World Allergy Organization. World allergy organization anaphylaxis guidelines: summary. *J Allergy Clin Immunol*. 2011;127(3):587-593.e22.

3. Simons FER. Anaphylaxis. *J Allergy Clin Immunol*. 2010;125(2)(suppl 2):S161-S181.
4. Sampson HA, Munoz-Furlong AM, 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*. 117:391-397.
5. Sicherer SH, Simons FER. Quandaries in prescribing an emergency action plan and self-injectable epinephrine for first-aid management of anaphylaxis in the community. *Allergy Clin Immunol*. 2005;115:575-583.
6. Gupta RS, Springston EE, Warrier MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics*. 2011; Jun 20 [Epub ahead of print].

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