

An important correction regarding EpiPen® (epinephrine) Auto-Injector

You may have seen an advertisement in this publication or on television about EpiPen Auto-Injector, for the emergency treatment of life-threatening allergic reactions (also known as anaphylaxis), that created the impression that a child who has peanut allergies can eat birthday cake with unknown ingredients and be worry free from the risk of anaphylaxis, if prepared with EpiPen.

The FDA said this was misleading and asked us to clarify.

EpiPen cannot prevent an allergic reaction. If you have life-threatening allergies, or care for a child who does, the most important step is to avoid your allergen altogether. Talk to your doctor about developing an anaphylaxis action plan.

EpiPen Auto-Injectors are for the emergency treatment of life-threatening allergic reactions—**anaphylaxis**—and for people who are at increased risk for these reactions. EpiPen and EpiPen Jr® (epinephrine) Auto-Injectors are intended for immediate self-administration as emergency supportive therapy, and are not a substitute for immediate medical care. When you have a life-threatening allergic reaction (anaphylaxis), use an EpiPen or EpiPen Jr Auto-Injector right away and immediately go to your doctor or emergency room for immediate medical treatment.

Visit epipen.com or call **855-EPIPEN-2** (855-374-7362) for more information.

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 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

Please see brief summary of the full Prescribing Information on adjacent page.

your doctor all the medicines you take, especially medicines for asthma. **If you have certain medical conditions, or take certain medications, your condition may get worse or you may have longer lasting side effects when you take the EpiPen or EpiPen Jr Auto-Injector.** 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.

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.

EPIPEN 2-PAK® EPIPEN Jr 2-PAK®

(Epinephrine) Auto-Injectors 0.3/0.15mg



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