

# fact sheet

## Mylan's Authorized Generic to EpiPen® (epinephrine injection, USP) Auto-Injector

### As part of Mylan's actions

#### to enhance access to

**epinephrine auto-injectors**, the company is planning to launch the first AG to EpiPen® Auto-Injector. Mylan will offer both the branded

EpiPen® Auto-Injector and AG

to EpiPen® Auto-Injector.

Epinephrine auto-injectors are

used for the emergency treatment

of a potentially life-threatening allergic reaction (anaphylaxis).

With epinephrine auto-injectors,

the stability of the medication and maintenance of quality of the

delivery device is critical given the

nature of the condition it is intended to treat. Following the launch of the

AG, Mylan anticipates that 85%

of prescriptions will shift to the

generic product. Mylan will launch

the generic once it has taken

reasonable steps to ensure sufficient

supply for the anticipated demand

for the product. Patients are

encouraged to work with their

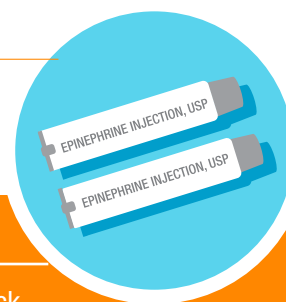
healthcare provider to determine

the best option for them.

### Branded Products vs. Authorized Generics (AG)

According to the U.S. Food and Drug Administration (FDA), generic drugs are equivalent to brand drugs in terms of dosage, safety, strength, quality, the way they work and the way they are administered. An AG is a brand-name prescription drug – already approved by FDA – and marketed as a generic under a private label. The AG is sold and distributed as a generic product. Unlike a standard generic, an AG has identical inactive ingredients to the branded product. The FDA approval of the branded product as safe and effective applies to the AG, as well.

### Mylan's Authorized Generic to EpiPen® Auto-Injector



Formulation	Identical to brand
Device	Identical to brand; sold as two-pack
Dosage	0.3 mg and 0.15 mg
Distribution	Retail Pharmacy, Wholesaler
Label	The label will be the same as the brand name (EpiPen®) but will not include the brand name. There are no changes to the administration instructions.
Approval Process	The AG will fall under Mylan's current New Drug Application for EpiPen® Auto-Injector as an annual reportable notification. The AG does not require an Abbreviated New Drug Application.
List Price	\$300 Final cost to patient dependent upon patient's insurance
Additional Resources Available	Patient Assistance Program

### Indications

EpiPen® (epinephrine injection, USP) 0.3 mg and EpiPen Jr® (epinephrine injection, USP) 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

Use EpiPen® or EpiPen Jr® Auto-Injectors right away when you have an allergic emergency (anaphylaxis). **Get emergency medical help right away.** You may need further medical attention.

**Please see additional Important Safety Information on next page.**

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## Mylan's Authorized Generic to EpiPen® (epinephrine injection, USP) Auto-Injector

### Important Safety Information, continued

Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. EpiPen® or EpiPen Jr® should **only** be injected into the middle of your outer thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Rarely, patients who have used EpiPen® or EpiPen Jr® may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breast-feeding or plan to breastfeed. Be sure to also tell your healthcare professional 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.®**

Common side effects include fast, irregular or "pounding" heartbeat, sweating, nausea or vomiting, breathing problems, paleness, dizziness, weakness, shakiness, headache, feelings of over excitement, nervousness or anxiety. These side effects usually go away quickly if you lie down and rest. **Tell your healthcare 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](http://www.fda.gov/medwatch) or call **1-800-FDA-1088**.

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