

EpiPen® (epinephrine) - First-Time Generic

- On August 29, 2016, Mylan announced its plans to launch an authorized generic version of EpiPen (epinephrine) autoinjector, for the treatment of life-threatening allergic reactions.
 - Mylan expects to launch generic EpiPen in several weeks, pending completion of labeling revisions.
 - Generic EpiPen will be available as a two-pack carton in both 0.15 mg and 0.30 mg strengths.
 Mylan also intends to continue to market and distribute branded EpiPen.
- EpiPen is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (eg, order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (eg, triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (eg, radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exerciseinduced anaphylaxis.
 - EpiPen is also available as a lower strength prefilled autoinjector (EpiPen Jr[®]), intended for patients weighing 15 to 30 kg.
 - Epinephrine injection is also available as <u>Adrenalin®</u>, <u>Auvi-Q™</u>, and various generics (vials, ampules and prefilled syringes). These products are not therapeutically equivalent to EpiPen.
- Since acquiring the rights to market EpiPen in 2007, Mylan has steadily raised the price for EpiPen. The
 price has increased by more than 500% over 8 years and currently lists at \$608.61.
 - Moreover, alternatives to EpiPen have been limited due to ongoing shortages. In late October 2015, Auvi-Q was recalled and temporarily discontinued.
- The wholesale acquisition cost (WAC) for generic EpiPen will be \$300 per generic, two-pack carton. Mylan intends to initiate a direct ship program in conjunction with the launch of its generic product.
- For brand EpiPen, a patient assistance program and a \$300 savings card will be available for certain patients.



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