

# FDA approves new, cheaper rival to EpiPen allergy shot

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This photo provided by Adamis Pharmaceuticals Corp. shows the Symjepi syringe, prefilled with the hormone epinephrine, which helps stop life-threatening allergic reactions from insect stings and bites or eating foods such as nuts and eggs. On Thursday, June 15, 2017, the Food and Drug Administration approved the Adamis Pharmaceuticals Corp. product, which is expected to go on sale later in 2017. (Audacity Health/Courtesy of Adamis Pharmaceuticals Corp. via AP)

U.S. regulators have approved new competition for EpiPen, the emergency allergy medicine that made Mylan a poster child for pharmaceutical company greed.

The Food and Drug Administration on Thursday approved Adamis Pharmaceuticals Corp.'s product, which should go on sale later this year.

Symjepi is a syringe prefilled with the hormone epinephrine, which helps stop life-threatening allergic reactions from insect stings and bites, foods such as nuts and eggs, or certain medications.

San Diego-based Adamis says its product is easier to use than Mylan's EpiPen, a spring-loaded syringe filled with a set dose that comes with a training device.

Symjepi also is smaller than EpiPen, so it's easier to fit in a pocket or purse. Most children and adults with severe food or insect allergies carry a device wherever they go and leave a spare at home, school or work.

Adamis said it is still lining up a distributor so it hasn't set the exact price for its product, which will be sold in pairs like EpiPen.

Adamis spokesman Mark Flather said Symjepi is intended to be a "low-cost alternative" to EpiPen and similar products, and the company is aiming to sell it for less than generic EpiPens.

In a note to investors, Evercore ISI analyst Umer Raffat wrote that Symjepi is not identical to EpiPen and so the price Adamis sets "will obviously be an important consideration."

Currently, EpiPens cost about \$630 to \$700 without insurance while the new generic version retails for about \$225 to \$425.

Mylan, which has U.S. headquarters near Pittsburgh, launched generic EpiPens last December in an effort to deflect mounting criticism.

Last summer, the company came under fire for repeatedly raising the price of EpiPens and CEO Heather Bresch was grilled by a Congressional panel.

Mylan hiked the price of a pair of EpiPens from \$94 in 2007, when the company acquired the product, to \$608 last year. The devices need to be replaced each year, adding to the financial sting.

Analysts and others have estimated that it costs less than \$20 to produce a pair of EpiPens.

While EpiPen has other rival products, doctors tend to prescribe EpiPen because it's so well known.

Just three years ago, EpiPens accounted for nearly 90 percent of both revenue and prescriptions filled in the U.S. for epinephrine injectors and syringes, according to QuintilesIMS, a pharmaceutical analytics company.

In the first quarter of this year, brand-name EpiPens only drew about 60 percent of epinephrine device prescriptions, while generic EpiPens—mostly Mylan's—had captured 38 percent of prescriptions.

Dr. Dennis J. Carlo, CEO of Adamis, said in a statement that his company is preparing to apply for FDA approval of a "junior version" of Symjepi. That would contain a lower epinephrine dose than Symjepi, and would compete with Mylan's EpiPen Jr.

Adamis, which specializes in developing medicines for respiratory disease and allergies, saw its shares surge more than 55 percent late

Thursday, to \$6.05.

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