



June 5, 2019

Important Update on EpiPen® (epinephrine injection, USP) 0.3 mg Auto-Injectors from Pfizer and Mylan

Temporary Extended Expiration Dates for All Lots of EpiPen® 0.3 mg Auto-Injectors and its Authorized Generic

To address continued shortages of EpiPen®, Pfizer and Mylan are coordinating with FDA to **extend the expiration dates by four months** of all lots of EpiPen® (epinephrine injection, USP) 0.3 mg Auto-Injectors and its authorized generic version currently on the market in the U.S. after a review of stability data. Patients should have confidence in using the products as Pfizer works to stabilize supply.

This announcement is based on a careful review of product stability data provided by Meridian Medical Technologies, Inc., a subsidiary of Pfizer, that manufactures EpiPen® Auto-Injectors and the authorized generic versions.

The affected lots, which have current expiration dates between February 2019 and October 2020, are listed in a table on the following page with their new expiration dates and can be found on FDA's website and EpiPen.com/EpiPenSupply. **The extension of the expiration dates does not apply to EpiPen Jr® (epinephrine injection, USP) 0.15 mg Auto-Injectors and its authorized generic version. Patients must continue to adhere to the manufacturer's expiry date labeled on EpiPen Jr® 0.15 mg and Epinephrine Injection, USP Auto-Injectors 0.15 products.**

EpiPen is a product that requires a highly complex and technical manufacturing and assembly process. Meridian continues to experience manufacturing challenges. These challenges are expected to result in tighter supplies and greater variability in pharmacy-level access over the coming weeks and will potentially continue through the summer months as seasonal demand increases.

We place great importance on the consistent availability of EpiPen for everyone who needs it and understand the frustration this ongoing situation continues to pose to patients, caregivers and schools. Our hope is that the expiration extension will help alleviate the shortage situation as Meridian continues its efforts to increase production and stabilize pharmacy inventories.

Mylan, the distributor, is expediting shipments upon receipt from Meridian and continues to encourage patients who are experiencing difficulty accessing product to call its Customer Relations team at 800-796-9526 for assistance in locating alternative pharmacies. Extended hours of operation are Monday through Friday, 8 a.m. to 7 p.m. ET.



IMPACTED PRODUCT

- **Epinephrine Injection, USP Auto-Injectors 0.3 mg**
NDC 49502-102-02 appears on the box
NDC 49502-102-01 appears on the individual device within the box
- **EpiPen® (epinephrine injection, USP) 0.3 mg Auto-Injectors**
NDC 49502-500-02 appears on the box
NDC 49502-500-01 appears on the individual device within the box

NEW EXTENDED EXPIRATION DATES

Manufacturer's Original Expiration Date	New Expiration Date <i>Please note: Expiration dates are valid through the last day of the month listed</i>
Feb 19	Jun 19
Mar 19	Jul 19
Apr 19	Aug 19
Jun 19	Oct 19
Jul 19	Nov 19
Aug 19	Dec 19
Sep 19	Jan 20
Oct 19	Feb 20
Nov 19	Mar 20
Dec 19 <i>(only available in Epinephrine Injection 0.3 mg)</i>	April 20
Jan 20	May 20
Feb 20 <i>(only available in Epinephrine Injection 0.3 mg)</i>	Jun 20
Mar 20 <i>(only available in Epinephrine Injection 0.3 mg)</i>	Jul 20
Apr 20	Aug 20
May 20 <i>(only available in Epinephrine Injection 0.3 mg)</i>	Sep 20
Jun 20	Oct 20
Aug 20 <i>(only available in Epinephrine Injection 0.3 mg)</i>	Dec 20
Sept 20	Jan 21
Oct 20 <i>(only available in Epinephrine Injection 0.3 mg)</i>	Feb 21

Sincerely,

Mace Rothenberg, M.D.
Chief Medical Officer, Pfizer

Rafael Muniz, M.D.
Head of Global Medical Affairs, Mylan Inc.