Pfizer Logo

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

Tuesday, November 23, 2021 - 12:10am

Extended Expiration Dates for Select Lots of EpiPen® 0.3 mg Auto-Injectors and Its Authorized Generic

To address shortages of EpiPen, Pfizer is coordinating with FDA to extend the expiration dates of specific lots of EpiPen® 0.3 mg Auto-Injectors and its authorized generic version after review of stability data. Patients should have confidence in using the products from these particular lots as Pfizer works to stabilize supply, which is anticipated in the fourth-quarter of 2018.

This announcement is based on a careful review of product stability data provided by Pfizer. We believe the extension of the expiration date will temporarily address patients' access to and use of EpiPen® 0.3 mg Auto-Injectors, and the authorized generic, particularly during back-to-school season as demand increases.

The affected lots, which have current expiration dates between April 2018 and December 2018, are indicated in the tables below with their new expiration dates and can be found on FDA's website.

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 of this strength. Patients should continue to adhere to the manufacturer's expiry date labeled on EpiPen Jr® 0.15 mg and Epinephrine Injection, USP Auto-Injectors 0.15 mg products.**

Please watch this important video from Pfizer's Chief Medical Officer, Dr. Freda Lewis-Hall, regarding this announcement.

Meridian, a subsidiary of Pfizer that manufactures EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors, and the authorized generic versions of these strengths, continues to experience manufacturing constraints affecting supply. Mylan and Pfizer place great importance on the consistent availability of EpiPen for everyone who needs it. Pfizer is working tirelessly to increase production and expedite shipments as rapidly as possible. Currently, supplies will vary from pharmacy to pharmacy, and we cannot guarantee that product will be available at all pharmacies.

We understand the challenges this situation continues to pose to patients. Ensuring continuity of the supply of our medicines is paramount.

Mylan, the distributor, is expediting shipments upon receipt from Pfizer 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 other pharmacies. To further assist patients during this period of limited supply, Mylan recently extended its Customer Relations hours to Monday through Friday, 8 a.m. to 7 p.m. ET.

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

Lot Number	Manufacturer's Original Expiry Date	New Expiration Date (beyond manufacturer's original expiry date)
6FM722	Apr 18	Aug 18
6FM739	Apr 18	Aug 18
6FM771	Apr 18	Aug 18
6FM772	Apr 18	Aug 18
6FM773	Apr 18	Aug 18
6FM715	May 18	Sep 18
6FM716	May 18	Sep 18
6FM756	May 18	Sep 18
6FM757	May 18	Sep 18
6FM768	May 18	Sep 18
6FM780	May 18	Sep 18
6FM781	May 18	Sep 18
6FM782	May 18	Sep 18
6FM783	May 18	Sep 18
6FM785	Jun 18	Oct 18
6FM787	Jun 18	Oct 18
7FM115	Aug 18	Dec 18
7FM117	Aug 18	Dec 18
7FM120	Aug 18	Dec 18
7FM134	Aug 18	Dec 18
7FM174	Sep 18	Jan 19
7FM175	Sep 18	Jan 19
7FM274	Oct 18	Feb 19
7FM275	Oct 18	Feb 19
7FM276	Oct 18	Feb 19

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

Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
6GM480	Apr 18	Aug 18
6GM481	Apr 18	Aug 18
6GM503	Apr 18	Aug 18

6GM504	Apr 18	Aug 18
6GM506	Apr 18	Aug 18
6GM507	Apr 18	Aug 18
6GM512	Apr 18	Aug 18
6GM669	Apr 18	Aug 18
6GM599	May 18	Sep 18
6GM685	Jun 18	Oct 18
6GM766	Jun 18	Oct 18
6GM767	Jun 18	Oct 18
7GM026	Aug 18	Dec 18
7GM045	Aug 18	Dec 18
7GM048	Sep 18	Jan 19
7GM054	Sep 18	Jan 19
7GM164	Sep 18	Jan 19
7GM172	Sep 18	Jan 19
7GM173	Sep 18	Jan 19
7GM272	Sep 18	Jan 19
7GM191	Oct 18	Feb 19
7GM200	Nov 18	Mar 19
7GM201	Nov 18	Mar 19
7GM203	Dec 18	Apr 19
7GM204	Dec 18	Apr 19
7GM212	Dec 18	Apr 19
7GM213	Dec 18	Apr 19
7GM360	Dec 18	Apr 19
7GM361	Dec 18	Apr 19