



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