FDA alerts consumers of nationwide voluntary recall of EpiPen and EpiPen Jr

The U.S. Food and Drug Administration is alerting consumers to Meridian Medical Technologies' voluntary recall of 13 lots of Mylan's EpiPen and EpiPen Jr (epinephrine injection) Auto-Injector products used for emergency treatment of severe allergic reactions. This recall is due to the potential that these devices may contain a defective part that may result in the devices' failure to activate. The recalled product was manufactured by Meridian Medical Technologies and distributed by Mylan Specialty.

While the number of reported failures is small, EpiPen products that potentially contain a defective part are being recalled because of the potential for life-threatening risk if a severe allergic reaction goes untreated. Consumers should keep and use their current EpiPens if needed until they get a replacement. Consumers should contact Mylan at 800-796-9526 or customer.service@mylan.com with any questions.

As stated on the product label, consumers should always seek emergency medical help right away after using their EpiPens, particularly if the device did not activate.

If you think you may be impacted by this recall, it is very important that you first contact Stericycle at 877-650-3494. Stericycle's hours of operation are Monday-Friday 8 a.m.-10 p.m. ET, and Saturday and Sunday 8 a.m.-5 p.m. ET.

- Stericycle will ask you questions about your EpiPen 2-Pak® or EpiPen Jr 2-Pak® cartons to confirm if the devices come from one of the recalled lots.
- Prior to calling Stericycle, you can confirm if you are in possession of a recalled EpiPen product by checking if the lot number matches any of the lot numbers listed in the table below. If so, you need to contact Stericycle at 877-650-3494. If not, your EpiPen product is not affected by the recall and there is no further action necessary.
- If you are in possession of a recalled EpiPen product, Stericycle will initiate the process of providing a container to return the recalled medication.
- Stericycle also will collect your contact information and will begin contacting patients back on Monday, April 3, with voucher information to redeem a free replacement product.
- Patients should not return any devices affected by the recall until they have received their voucher to redeem their free replacement from their pharmacy. It is important that patients continue to carry their current EpiPen Auto-Injector until they receive a replacement device.

Patients may receive either EpiPen Auto-Injector or Mylan's authorized generic for EpiPen Auto-Injector at the pharmacy as a replacement based on availability. The authorized generic has the exact same drug formulation, has the exact same operating instructions and is therapeutically equivalent to EpiPen Auto-Injector, and may be substituted for EpiPen Auto-Injector.

Mylan is committed to replacing recalled devices at no cost and Mylan would like to reassure patients that there will be no additional replacement-related financial burden to them as a result of this recall.
Please check back here for any updates and additional information on the product return and replacement process.

Recall Details

Meridian Medical Technologies, a Pfizer company and Mylan's manufacturing partner for EpiPen®Auto-Injector, has expanded a voluntary recall of select lots of EpiPen (epinephrine injection, USP) and EpiPen Jr® (epinephrine injection, USP) Auto-Injectors to now include additional lots distributed in the U.S. and other markets in consultation with the U.S. Food and Drug Administration (FDA).
The recall impacts certain lots of the 0.3 mg and 0.15 mg strengths of EpiPen Auto-Injector. None of the recalled lots include the authorized generic for EpiPen Auto-Injector, which is also manufactured by Meridian Medical Technologies.

Product/Dosage	NDC Number on Carton	Lot Number	Expiration Date
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	5GN767	April 2017
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	5GN773	April 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	5GM631	April 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	5GM640	May 2017
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	6GN215	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM082	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM072	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM081	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM088	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM199	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM091	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM198	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM087	October 2017

The lot number is located on both the 2-Pak carton and the auto-injector. If the recalled EpiPen®Auto-Injector is still contained in the carton, refer to the left flap on the carton, which is black in color. You will find the lot number written in white and preceded by the word 'LOT.'
On the auto-injector itself, you will find the lot number towards the top of the label in black and preceded by the word 'LOT.'
NOTE: The NDC on the box ends with "2" because it contains two EpiPen Auto-injectors. The NDC on the individual EpiPen within the box has an NDC ending in "1."

Additional Information

For additional information, please see the press release.

Patient and Customer Contact

To return your product, please contact Stericycle at 877-650-3494. If you have any additional questions regarding this recall, please contact Mylan Customer Relations at 800-796-9526 or customer.service@mylan.com.