Mylan

URGENT: DRUG RECALL

EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg
EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg

Recall initiated by the Manufacturer: Meridian Medical Technologies, a Pfizer Company
Recall conducted by: Mylan Specialty L.P.
Product distributed by: Mylan Specialty L.P.

April 3, 2017

PRODUCT

NDC	Name	Lot	Expires
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	5GM631	April 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	5GM640	May 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM072	September 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM081	September 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM082	September 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM087	October 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM088	October 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM091	October 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM198	October 2017
49502-500-02	EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg	6GM199	October 2017
49502-501-02	EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg	6GN215	September 2017
49502-501-02	EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg	5GN767	April 2017
49502-501-02	EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg	5GN773	April 2017

REASON

Mylan Specialty L.P. announced that 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).

This recall is being conducted as a result of the receipt of two previously disclosed reports outside of the U.S. of failure to activate the device due to a potential defect in a supplier component. The potential defect could make the device difficult to activate in an emergency (failure to activate or increased force needed to activate) and have significant health consequences for a patient experiencing a life-threatening allergic reaction (anaphylaxis). Both reports are related to the single lot that was previously recalled. The incidence of the defect is extremely rare and testing and analysis across the potentially impacted lots has not identified any units with a defect. However, the recall is being expanded to include additional lots as a precautionary measure out of an abundance of caution.

The recalled product was manufactured by Meridian Medical Technologies, a Pfizer company, and distributed by Mylan Specialty between December 2015 and July 2016. The expanded voluntary recall is being initiated in the U.S. and also will extend to additional markets in Europe, Asia, North and South America.

EpiPen and EpiPen Jr (epinephrine injection) Auto-Injectors are used in the emergency treatment of allergic reactions (Type I) including anaphylaxis.

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EpiPen® (epinephrine injection, USP) Auto-Injectors 0.3 mg
EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg

ACTION

Wholesaler: Immediately examine your inventory, quarantine and discontinue distribution of these lots. In addition, if you have further distributed the product, please identify your retail level customers and notify them of this product recall. Please provide a list of customers via Microsoft excel file to mylan4403@stericycle.com within 10 business days. Stericycle will notify your retail level customers that received the affected batches.

Retailer: Immediately examine your inventory, quarantine and discontinue distribution of these lots. Additionally, if you have further distributed the product, please identify the consumer and notify them immediately of this product recall. The consumer should be instructed to contact Stericycle at 877-650-3494 for the documentation packet to return the product to Stericycle and to receive a product voucher for replacement product.

Consumer: Please contact Stericycle at 877-650-3494 for the documentation packet to return the product to Stericycle and to receive product voucher for replacement product.

Wholesaler, Retailer and Consumer: Please proceed to items 1, 2, and 3 listed below.

1. Carry out a physical count and record this data on the Business Reply Card and the Packing Slip which are included with this letter.
2. Mail the postage paid Business Reply Card to the address provided.
3. Return the recalled product with the Packing Slip using the prepaid UPS Return Service shipping labels to:

Stericycle
Event # 3839
2670 Executive Drive, Suite A
Indianapolis, IN 46241

OTHER

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. Patients, customers and distributors are being notified and should refer to Mylan.com/EpiPenRecall for updates on product return and replacement instructions. We are asking patients to keep their existing product until their replacement product can be secured.

Patients may receive either EpiPen Auto-Injector or the 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.

It is important that patients continue to carry their current EpiPen Auto-Injector until they receive a replacement device.

This recall extends to the consumer level with the knowledge of the U.S. Food and Drug Administration.

For questions regarding the recall, please call Stericycle at 877-650-3494.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

EpiPen® (epinephrine injection, USP) Auto-Injectors

NDC #	LOT	QTY	NDC #	LOT	QTY
49502-500-02 (2-Pack NDC) 49502-500-01 (Individual Unit NDC)	5GM631		49502-500-02 (2-Pack NDC) 49502-500-01 (Individual Unit NDC)	6GM088	
	5GM640			6GM199	
	6GM082			6GM091	
	6GM072			6GM198	
	6GM081			6GM087	
49502-501-02 (2-Pak NDC) 49502-501-01 (Individual Unit NDC)	5GN767		49502-501-02 (2-Pak NDC) 49502-501-01 (Individual Unit NDC)	6GN215	
	5GN773				

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, **even if you do not have the recalled product. Thank you**

Name: _____ Title: _____ Phone: _____

Wholesaler Debit Memo: _____ Signature: _____

BUSINESS REPLY CARD

Mylan Pharmaceuticals, Inc.

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

EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg

April 3, 2017

Event 3839 ID 55689966

LIFE ASSIST INC

B55689966-90

EpiPen® (epinephrine injection, USP) Auto-Injectors

NDC #	LOT	QTY	NDC #	LOT	QTY
49502-500-02 (2-Pack NDC) 49502-500-01 (Individual Unit NDC)	5GM631		49502-500-02 (2-Pack NDC) 49502-500-01 (Individual Unit NDC)	6GM088	
	5GM640			6GM199	
	6GM082			6GM091	
	6GM072			6GM198	
	6GM081			6GM087	
49502-501-02 (2-Pak NDC) 49502-501-01 (Individual Unit NDC)	5GN767		49502-501-02 (2-Pak NDC) 49502-501-01 (Individual Unit NDC)	6GN215	
	5GN773				

The following information is required to assure proper crediting:

Wholesaler Debit Memo: _____

Direct Account #: _____

Indirect Account Info: _____

PACKING SLIP

Mylan Pharmaceuticals, Inc.

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

EpiPen Jr® (epinephrine injection, USP) Auto-Injectors 0.15 mg

April 3, 2017

Event 3839 ID 55689966

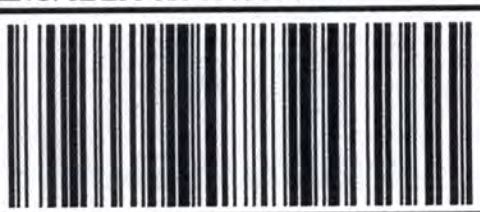
LIFE ASSIST INC

Ship STERICYCLE
To:
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
ID: 55689966
Event: 3839
Seq.# 90

IN 462 9-01

UPS GROUND
TRACKING: 1Z E38 010 06 9981 7058



PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All follow-up will be based on this shipping information.

TRACKING: 1Z E38 010 06 9981 7058

ID 55689966 Event 3839
LIFE ASSIST INC

GTY-04-12