Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 6, 2016

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: PharMEDium Services, LLC – RECALL [Drug]

AFFECTED PRODUCT: 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag

SUMMARY: **Unclassified Recall; The recall has been initiated because products that have been found to exhibit a slight discoloration in the admixture. The drug manufacturer's prescribing information advises not to use the product if it is discolored.**

The affected 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag include the following lot numbers and expiration dates:

2K6134	
Lot#	Expiration Date
15342084S	2/10/2016
15342191S	2/10/2016
15342223S	2/10/2016
15342224S	2/10/2016
15342225S	2/10/2016
15342226S	2/10/2016
15343025S	2/11/2016
15343026S	2/11/2016
15343129S	2/11/2016
15343131S	2/11/2016
15344157S	2/12/2016
15344160S	2/12/2016
15344209S	2/12/2016
15345036S	2/13/2016
15345104S	2/13/2016
15345106S	2/13/2016
15345142S	2/13/2016
15346015S	2/14/2016
15346016S	2/14/2016
15346017S	2/14/2016
15346018S	2/14/2016
15346019S	2/14/2016

2K6134	
Lot#	Expiration Date
15346020S	2/14/2016
15346022S	2/14/2016
15346023S	2/14/2016
15348152S	2/16/2016
15348197S	2/16/2016
15350046S	2/18/2016
15350154S	2/18/2016

2K6127	
Lot#	Expiration Date
15342123S	2/10/2016
15349071S	2/10/2016
15351050S	2/10/2016

SUGGESTED ACTION: **For consumer inquiry only. Hospitals or other healthcare providers with questions regarding this recall can contact PharMEDium Services by calling 847-457-2244 or email at quality1@pharmedium.com Monday through Friday, 8:00 AM to 5:00 PM, Central Standard Time. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Pharmedium Issues Voluntary Nationwide Recall of 4mg Norepinephrine Bitartrate (16mcg/mL) Added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 8mg Norepinephrine Bitartrate (32mcg/mL) Added to 0.9% Sodium Chloride in 250mL Viaflex Bag for Discoloration.

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

December 31, 2015

Contact

Consumers

Thomas Rasnic
847-457-2256

Firm Press Release
View Product Photos

Lake Forest, IL PharMEDium Services, LLC is voluntarily recalling 29 lots of 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 3 lots of 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag distributed to hospital customers. We have received complaints from hospitals for products that have been found to exhibit a slight discoloration in the admixture. The drug manufacturer's prescribing information advises not to use the product if it is discolored.

Discoloration is indicative of degradation and could result in decreased potency due to oxidation of Norepinephrine Bitartrate. Decreased potency may result in a delay of achieving desired therapeutic effect. PharMEDium Services has not received any reports of adverse events to date related to this recall.

The product is used for blood pressure control in certain acute hypotensive states and is packaged in a 250 mL Viaflex Bag. The affected 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag include the following lot numbers and expiration dates:

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15343131S	2/11/2016
15344157S	2/12/2016
15344160S	2/12/2016
15344209S	2/12/2016
15345036S	2/13/2016
15345104S	2/13/2016
15345106S	2/13/2016
15345142S	2/13/2016
15346015S	2/14/2016
15346016S	2/14/2016
15346017S	2/14/2016
15346018S	2/14/2016
15346019S	2/14/2016
15346020S	2/14/2016
15346022S	2/14/2016
15346023S	2/14/2016
15348152S	2/16/2016
15348197S	2/16/2016
15350046S	2/18/2016
15350154S	2/18/2016
2K6127	
Lot#	**Expiration Date**
15342123S	2/10/2016
15349071S	2/10/2016
15351050S	2/10/2016

The product can be identified by PharMEDium Services Code 2K6134 (NDC Number 61553-134-61) 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag or 2K6127 (NDC 61553-127-61) 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag

On December 22, 2015, PharMEDium Services e-mailed notification to all affected customers and requested quarantine and destruction. Replacement of all recalled products is available.

Hospital pharmacies that have the recalled 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag in stock should stop using and discard per the hospital destruction policy. Hospitals that may have shared these products with other hospitals should contact those hospitals that received the products.

Hospitals or other healthcare providers with questions regarding this recall can contact PharMEDium Services by calling 847-457-2244 or email at quality1@pharmedium.com Monday through Friday, 8:00 AM to 5:00 PM,

Central Standard Time. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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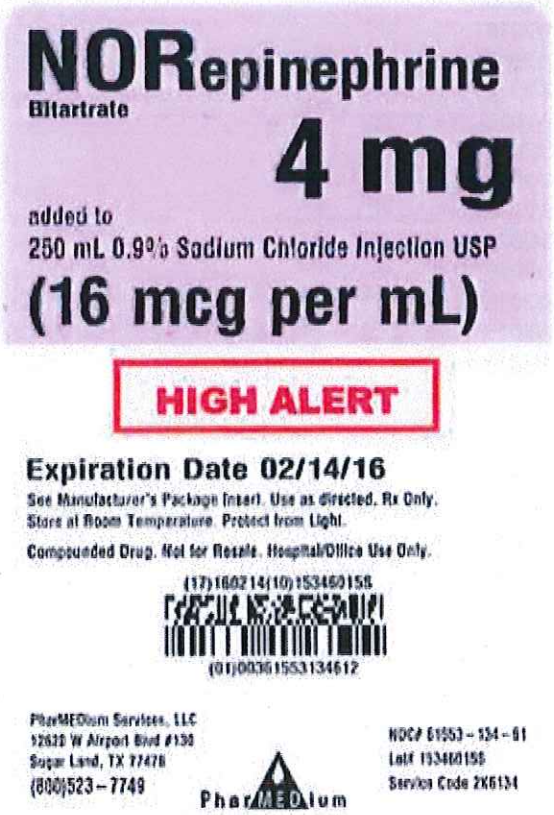
Product Photos



NORepinephrine Bitartrate 8 mg

added to

250 mL 0.9% Sodium Chloride Injection USP

(32 mcg per mL)

HIGH ALERT

Expiration Date 02/10/16

See Manufacturer's Package Insert. Use as directed. Rx Only.
Store at Room Temperature. Protect from Light.

Compounded Drug. Not for Resale. Hospital/Office Use Only

(17)160210(10)153421235

(01)00361553127614

PharMEDium Services, LLC
12620 W Airport Blvd #130
Sugar Land, TX 77478
(800)523-7749

PharMEDium

NDC# 61553-127-61
Lot# 153421235
Service Code 2K6127