



Michael R. Pence
Governor
Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 2, 2015
TO: All Local Health Departments
Attr: Chief Food Inspection Officer
FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Valeant Pharmaceuticals North America LLC - RECALL [Drug]

AFFECTED PRODUCT: Virazole® (ribavirin powder for solution), 100 mL

SUMMARY: Unclassified Recall; The product is being recalled due to microbial contamination.

Virazole is packaged in 100 mL, 6 g Vial, 4-pack NDC 00187-0007-14 which is to be reconstituted with 300 mL Sterile Water for Injection or Sterile Water for Inhalation (no preservatives added) and administered only by a small particle aerosol generator (SPAG-2). The affected Virazole lot is Lot No. 340353F with an expiration date of Oct-2018.

Virazole was distributed in the U.S.

SUGGESTED ACTION: For consumer inquiry only. Customers with questions regarding this recall can contact VPNA by phone at 800-321-4576 Monday - Friday, 8am - 5pm (Eastern) or by e-mail address at pharmcs@valeant.com.

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.

Valeant Pharmaceutical North America LLC Issues Voluntary Nationwide Recall of Virazole® (Ribavirin Powder For Solution) Due to Microbial Contamination

Contact:
Consumer:
877-361-2719

FOR IMMEDIATE RELEASE - December 31, 2014 - Bridgewater, New Jersey - Valeant Pharmaceuticals North America LLC (VPNA) is issuing a voluntarily recall of one lot of Virazole® (ribavirin powder for solution), 100 mL, 6g Vial, 4-pack to the user level.



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To promote and provide
essential public health services.

Inhalation of a non-sterile product with microbial contamination into the airways could increase the risk of respiratory infection. The risk is higher in patients who are immunocompromised (because of underlying disease), and are more susceptible.

Virazole is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV). Valeant has not received reports of adverse events or injuries, related to this recall.

Virazole is packaged in 100 mL, 6 g Vial, 4-pack NDC 00187-0007-14 which is to be reconstituted with 300 mL Sterile Water for Injection or Sterile Water for Inhalation (no preservatives added) and administered only by a small particle aerosol generator (SPAG-2). The affected Virazole lot is Lot No. 340353F with an expiration date of Oct-2018. Virazole was distributed in the U.S. and Australia.

VPNA is notifying its distributors and customers by mail and is arranging for return of all recalled product of this lot. This recall only affects this lot of Virazole; all other lots are not affected and are not involved in this recall.

Customers with questions regarding this recall can contact VPNA by phone at 800-321-4576 Monday - Friday, 8am - 5pm (Eastern) or by e-mail address at pharmcs@valeant.com. Consumers should contact their physician or healthcare provider for questions regarding this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to VPNA at 877-361-2719 or to the FDA's MedWatch Adverse Event Reporting program as follows:

- 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 in conjunction with the U.S. Food and Drug Administration.

About Valeant Pharmaceuticals North America LLC:

Valeant Pharmaceuticals North America LLC, is a specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, eye health, consumer healthcare and other pharmaceutical products. More information about Valeant can be found at www.valeant.com.

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