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NEW DRUG FAX SHEET

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Volume 20 (Issue 1) SPECIAL ISSUE January 5, 2015

MICROBIAL CONTAMINATION: VIRAZOLE (RIBAVIRIN POWDER FOR SOLUTION) BY VALEANT PHARMACEUTICAL NORTH AMERICA, LLC

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding a voluntary recall of ribavirin powder for solution from Valeant Pharmaceuticals North America, LLC, due to microbial contamination. If you need further information please contact the Samford University Global Drug Information Service at (205) 726-2659.

AUDIENCE: Pharmacy, Hepatology, Infectious Disease

ISSUE: Valeant Pharmaceuticals North America LLC (VPNA) is issued a voluntarily recall of one lot of Virazole (ribavirin powder for solution), 100 mL, 6g Vial, 4-pack to the user level.

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.

BACKGROUND: Virazole is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV).

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.

RECOMMENDATION: 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.

Healthcare professionals are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form 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.

Read the MedWatch safety alert, including a link to the Press Release, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm428700.htm

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