

Dear U.S. Healthcare Professional

November 19, 2009

Subject: Recall of Sinex VapoSpray 12-hour Decongestant Ultra Fine Mist Nasal Spray 15 ml Lot # 9239028831



The Procter & Gamble Company is voluntarily recalling three lots of its Vicks Sinex nasal spray in three countries: the United States, Germany and the United Kingdom. The one lot affected in the United States is listed below. The lot number is printed on the outer carton and the bottle. We are conducting this recall at the patient, retail, and wholesaler level.

The safety of consumers is our primary focus. P&G is taking this precautionary step after finding the gram-negative bacteria *Burkholderia cepacia* (*B. cepacia*) in a small amount of product made at our plant in Gross Gerau, Germany. There have been no reports of illness. However, the bacteria could cause serious infections for anyone with a compromised immune system, or those with chronic lung conditions, such as cystic fibrosis. *B. cepacia* poses little medical risk to healthy individuals.

We detected this problem during a routine quality control check at the plant and promptly took action. The bacteria *B. cepacia* was found in a small amount of product from U.S. Lot 9239028831. P&G is conducting testing on the U.K. and German lots that have been produced from the same batch of raw material mixture. The company's analysis to date shows this problem is limited to a

single batch of raw material mixture involving three lots of product. These three lots were sold only in the United States, Germany and the United Kingdom.

We are removing the product in question from store shelves and have informed regulatory authorities in the affected countries. P&G is advising consumers who have used the identified product and have concerns to contact their healthcare providers. We are asking for your assistance as follows:

Recalled Product in U.S.
Vicks Sinex VapoSpray 12 hour Decongestant Ultra Fine Mist Nasal Spray 15 ml
Production Lot: 9239028831
UPC Code: 323900012530
Expiration Date: 08/2012

Healthcare Professionals:

- a. **Your patients should be advised to immediately stop using any Sinex VapoSpray 12-Hour Decongestant Ultra Fine Mist Nasal Spray from Lot # 9239028831.** Consumers should simply discard the affected product as they would any OTC medicine. Consumers should not return this product to their store or pharmacy.
- b. **P&G has established two toll-free phone numbers to handle all communications related to this recall: Consumers should call 1-877-876-7881** - Please share this number with any patients who contact you so they can receive answers to their questions and also receive a replacement coupon or refund.

Healthcare Professionals should call 1-800-873-8276 to receive answers to any of your questions related to this matter.

Any adverse events with the use of this product and/or quality problems should be reported via FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787, or on the MedWatch Website at www.fda.gov/medwatch.

- c. **Pharmacists: please help us remove any Sinex VapoSpray 12-hour Decongestant Ultra Fine Mist Nasal Spray 15 ml - Lot # 9239028831 from your pharmacy shelves.** P&G has sent information to our retail customers and wholesalers on how to return this product.

Information about this recall is also posted on our website www.vicks.com. We apologize for any inconvenience this recall may cause and we thank you for your cooperation.

Sincerely,

Jenelle Sobotka, Pharm.D.
Manager, Professional Relations
The Procter & Gamble Company