




Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 9, 2013

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

FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: McNeil Consumer Healthcare Recall [Drug]

AFFECTED PRODUCT Concentrated MOTRIN Infants' Drops Original Berry Flavor 1/2 fl oz bottles
Lot Numbers DCB3T01, DDB4R01, AND DDB4S01 Due to Plastic Particles In the Bottles

SUGGESTED ACTION:

Unclassified Recall; McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. ("McNeil") is voluntarily recalling at the retail level three lots, approximately 200,000 bottles, of Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz bottles distributed in the United States (see full product list below). After releasing these three lots of Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz into the market, tiny plastic particles (approximately 1 mm in size or about the size of a poppy seed) were identified in a different product lot during manufacturing. This lot was not released to the market. It was determined that the particles originated in a shipment from a third party supplier of ibuprofen, the active ingredient in Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz. A list of the recalled products is listed below. Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The prescription preparations were distributed in the United States. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-3213.

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.



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

McNeil Consumer Healthcare Announces Voluntary Recall of Three Lots of Concentrated MOTRIN Infants Drops Original Berry Flavor 1/2 fl oz.

Contact

Consumer:
1-877-414-7709

FOR IMMEDIATE RELEASE - September 6, 2013 - McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. ("McNeil") is voluntarily recalling at the retail level three lots, approximately 200,000 bottles, of Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz bottles distributed in the United States (see full product list below). This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA). McNeil is asking retailers to remove the affected lots from store shelves, and is asking consumers to stop using and dispose of any product they may have that is included in this recall.

FULL RECALLED PRODUCT LIST:

Product	Lot #	UPC Code	Case UPC Code
Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz bottles NDC 50580-100-18	DCB3T01	300450524157	30300450524158
	DDB4R01		
	DDB4S01		

After releasing these three lots of Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz into the market, tiny plastic particles (approximately 1 mm in size or about the size of a poppy seed) were identified in a different product lot during manufacturing. This lot was not released to the market. It was determined that the particles originated in a shipment from a third party supplier of ibuprofen, the active ingredient in Concentrated MOTRIN® Infants' Drops Original Berry Flavor 1/2 fl oz. Out of an abundance of caution, McNeil is voluntarily recalling the three lots released to the market made with the same batch of active ingredient. McNeil has worked with the third party to ensure that corrective measures are currently in place and are effective. The potential for adverse medical events related to the reason for this recall is not likely. Concentrated Infants' MOTRIN® Drops Dye-Free Berry Flavor 1 fl oz is not included in this recall. Children's or Adult MOTRIN® products are not included in this recall.

Adverse events that may be related to the use of this product may be reported to U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- **Online:** www.fda.gov/medwatch/report.htm¹
- **Regular mail:** Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178.

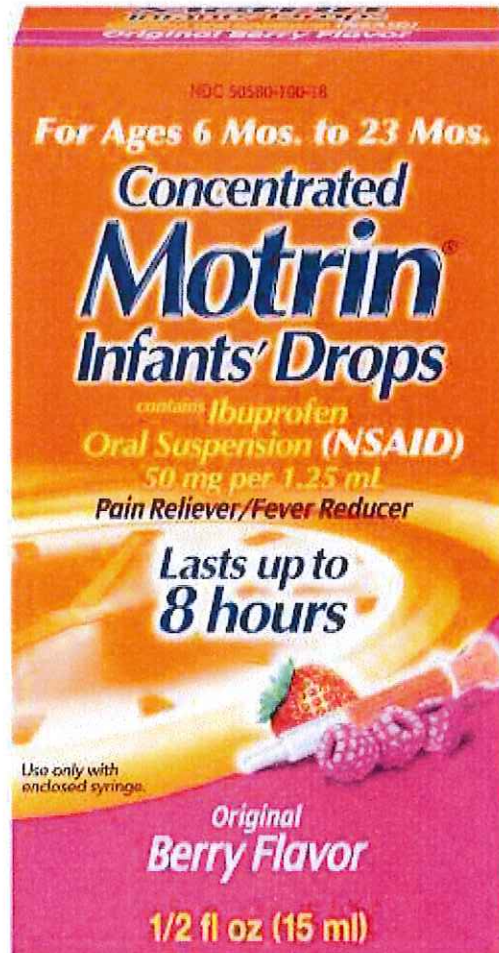
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RSS Feed for FDA Recalls Information³ [what's this?]⁴

Photo: Product Labels⁵

Recalled Product Photos Are Also Available on FDA's [Flickr Photostream](#).⁶

**McNeil Consumer Healthcare Announces Voluntary Recall of Three Lots of Concentrated MOTRIN Infants Drops Original Berry Flavor 1/2 fl oz.
Photo**



[Return to Firm Press](#)¹