

Novartis Consumer Health, Inc. (NCH) announced today that it is voluntarily recalling all lots of select bottle packaging configurations of Excedrin® and NoDoz® products with expiry dates of December 20, 2014 or earlier as well as Bufferin® and Gas-X Prevention® products with expiry dates of December 20, 2013 or earlier, in the United States. NCH is taking this action as a precautionary measure because the products may contain stray tablets, capsules, or caplets from other Novartis products, or contain broken or chipped tablets. The Novartis Consumer Health Inc. Lincoln, NE facility has voluntarily suspended operations and shipments to accelerate maintenance and other improvement activities at the site. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Mixing of different products in the same bottle could result in consumers taking the incorrect product and receiving a higher or lower strength than intended or receiving an unintended ingredient. This could potentially result in overdose, interaction with other medications a consumer may be taking, or an allergic reaction if the consumer is allergic to the unintended ingredient. NCH is not aware of adverse events reported with the issues leading to the recall. These over-the-counter products were distributed nationwide to wholesalers and retailers. Novartis Consumer Health Inc. is notifying its distributors and customers and is arranging for return of all recalled products. Wholesalers and retailers should stop distribution and return the affected product using Novartis Product Return information that is being provided to them.

Consumers that have the recalled product(s) should stop using the product(s) and contact the Novartis Consumer Relationship Center at 1-888-477-2403 for information on how to return the affected products and receive a full refund. A consumer website, [www.novartisOTC.com](http://www.novartisOTC.com), provides additional information. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products. Adverse events that may be related to the use of these products may be reported to FDA's MedWatch Adverse Event Reporting Program online, by regular mail or by fax:

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)  
 Mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

**Products Affected by the Novartis Brand Recall**

Bufferin Extra Strength Tablets	Bufferin Low Dose Tablets	Bufferin Regular Strength Tablets
Excedrin Extra Strength Caplets	Excedrin Back&Body Caplets	Excedrin Extra Strength Express Gel Caplets
Excedrin Extra Strength Gel Tablets	Excedrin Extra Strength Tablets	Excedrin Migraine Express Gel Caplets
Excedrin Migraine Caplets	Excedrin Migraine Gel Tablets	Excedrin Migraine Tablets
Excedrin PM Tablets	Excedrin PM Caplets	Excedrin PM Gel Caplets
Excedrin Sinus Headache Caplets	Excedrin Tension Headache Caplets	Excedrin Tension Headache Express Gel Caplets
Excedrin Tension Headache Gel Tablets	Gas-X Prevention	NoDoz Maximum Strength Tablets

**References:**

- Novartis OTC Consumer Product Updates Website. Novartis, Inc. Accessed 1/9/2012. Available at <http://www.novartis-otc.com/otc/index.html>
- Food and Drug Administration (FDA). Recalls, Market Withdrawals, & Safety Alerts. Accessed 1/9/2012. Available at: <http://www.fda.gov/Safety/Recalls/default.htm>