

Excedrin[®]/Bufferin[®] Voluntary Recall

(Including NoDoz[®] and Gas-X[®])

IMPORTANT NOTICE

On January 8, 2012, Novartis Consumer Health, Inc. issued a voluntary recall of all lots of various over-the-counter (OTC) products, including Excedrin (acetaminophen, aspirin, caffeine), Bufferin (aspirin, calcium carbonate, magnesium oxide, magnesium carbonate), NoDoz[®] (caffeine), and Gas-X[®] (simethicone) due to concerns over manufacturing complications.

BACKGROUND

Novartis Consumer Health, Inc. has issued a voluntary recall of various over-the-counter products secondary to patient complaints of broken or chipped tablets. Novartis further indicates that retail containers labeled for these products may contain mixed or foreign capsules, caplets, or tablets, including opioid pain relievers, secondary to inconsistent packaging practices at the manufacturer's Nebraska facility. The following products have been identified as those which may be affected:

| Drug Product | Expiration Date |
|---|--------------------------------|
| Excedrin [®] Extra Strength Caplets, Excedrin [®] Extra Strength Express Gel Caplets, Excedrin [®] Extra Strength Gel Caplets, Excedrin [®] Extra Strength Tablets, Excedrin [®] Back & Body Caplets, Excedrin [®] Sinus Headache Caplets, Excedrin [®] Migraine Caplets, Excedrin [®] Migraine Gel Tablets, Excedrin [®] Migraine Tablets, Excedrin [®] Menstrual Complete Express Gel Caplets, Excedrin [®] PM Caplets, Excedrin [®] PM Express Gel Caplets, Excedrin [®] PM Tablets | On or before December 20, 2014 |
| NoDoz [®] | |
| Bufferin [®] Extra Strength Tablets, Bufferin [®] Low Dose Tablets, Bufferin [®] Regular Strength Tablets | On or before December 20, 2013 |
| Gas-X [®] | |

Novartis indicates that no adverse events have been reported, thus far, pursuant to the identification of the manufacturing inconsistencies noted above. The possible presence of mixed products in consumer retail containers may lead to the inadvertent consumption of more or less medication than intended. This may result in patients experiencing over-dose/under-dose situations, drug-drug interactions, or allergic reactions if a patient is allergic to the unintended drug product. Operations and product shipments from Novartis' Nebraska facility have been temporarily suspended pending correction of the manufacturing errors identified. Novartis indicates that it is monitoring updates to quality standards at all of its manufacturing facilities.



RECOMMENDED ACTIONS

PMSI Actions

At this point in time, there are no action steps recommended by Novartis for distributors, wholesalers, and retail outlets carrying the identified drug products. Given the over-the-counter status of the affected products, it is expected that payors will not experience any significant financial impact as a result of this voluntary recall.

Patient Actions

All patients who are in possession of the affected drug products should cease using them immediately and contact Novartis' consumer relationship center at 1-888-477-2403 to receive information regarding the process for returning them to the manufacturer. All patients utilizing the aforementioned brand name products, regardless of expiration date, should inspect the contents of containers in their possession to ensure that all tablets, capsules, and caplets have the same shape, size, color, and markings. Any variation in these factors should signal a potential concern; therefore, patients are advised to visit their pharmacist for product identity verification.

CONCLUSION

This PMSI Drug Alert is made available by our clinical pharmacist team to provide you pertinent drug information and identify the potential impact on your injured workers' care and your costs. As your pharmacy partner, PMSI understands the importance of staying on top of breaking news in the pain management arena and keeping you informed. We will continue to monitor and regularly communicate our proactive response to FDA recommendations to help protect your interests.

DISCLAIMER

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REFERENCES

Novartis Consumer Health Inc. voluntarily recalls certain over-the-counter products in the US while Novartis Group strengthens quality standards across all manufacturing sites. Novartis media releases. <http://www.novartis.com/newsroom/media-releases/en/2012/1575836.shtml> <Accessed January 9, 2012>

Novartis Consumer Health Over-The-Counter Products: Recall – Potential Presence of Foreign Tablets or Chipped or Broken Tablets or Gelcaps. FDA Recall – Firm Press Release. <http://www.fda.gov/Safety/Recalls/ucm286240.htm?source=govdelivery> <Accessed January 9, 2012>

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