

Drug Alert

Issued January 2012



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Pharmacy

Medical Services
and Equipment

Settlement Solutions

Endo Pharmaceuticals Packaging Error (mislabeled opioid products)

IMPORTANT NOTICE

On January 9, 2012, the Food and Drug Administration (FDA) issued a public safety announcement indicating that commercial containers for various opioids packaged for Endo Pharmaceutical by Novartis Consumer Health may contain products other than those listed on the container label.

BACKGROUND

Secondary to packaging inconsistencies identified at Novartis' Consumer Health facility in Lincoln, Nebraska, the FDA has indicated that commercial containers for various opioid pain relievers packaged at the facility may contain opioid products other than those listed on the product label. On January 8, 2012, Novartis indicated similar packaging quality control concerns with various over-the-counter drug products, including Excedrin[®], Bufferin[®], Gas-X[®], and NoDoz[®]. Sources now indicate that even these over-the-counter products may inadvertently contain opioid pain relievers. A list of the potentially affected opioid products is provided below:

Drug Name	NDC
Opana [®] ER (oxymorphone)	63481-907-70, 63481-674-70, 63481-617-70, 63481-571-70, 63481-693-70
Opana [®] (oxymorphone)	63481-612-70, 63481-613-70, 60951-794-70, 60951-795-70
Percocet [®] (oxycodone-acetaminophen)	63481-627-70, 63841-623-75, 63481-623-70, 63481-623-85, 63481-628-70, 63481-621-70, 63481-622-70, 63481-629-70
Percodan [®] /Endodan [®] (oxycodone-aspirin)	63481-121-70, 60951-310-70
Endocet [®] (oxycodone-acetaminophen)	60951-796-70, 60951-700-70, 60951-797-70, 60951-712-70, 6051-602-70, 60951-602-85
Morphine Sulfate extended-release (generic only)	60951-652-70, 60951-653-70, 60951-655-70, 60951-658-70, 60951-659-70
Zydone [®] (hydrocodone-acetaminophen)	63481-668-70, 63481-669-70, 63481-698-70



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Opioids are potent pain-relieving agents attainable only under the direct supervision and provision of a prescription from a licensed healthcare professional. Endo indicates that they are not aware of any current patients experiencing a confirmed medication mix-up or adverse events as a direct result of this alert. The manufacturer indicates that short-term product unavailability may be possible as a direct result of the Nebraska facility shut-down.

RECOMMENDED ACTIONS

PMSI Actions

At this time, Endo Pharmaceuticals recommends that dispensing pharmacies visually inspect their stock of the potentially affected drug products in a container other than the manufacturer's bottle. PMSI is complying with Endo's recommendations to ensure the safety of our patients. Given the generic availability of most of the affected products, it is not expected that payors will experience any significant financial impact as a result of this action.

Patient Actions

Patients are encouraged to contact the pharmacy from which the affected products may have been dispensed for questions relating to medication identity verification. Patients may visit www.endo.com to see a photographic listing of these products depicting their shape, color, and individual markings.

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

Endo Pharmaceuticals Opiate Products by Novartis Consumer Health: Public Health Advisory – Potential Safety Risk. FDA MedWatch. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm286280.htm?source=govdelivery> <Accessed January 9, 2012>

Opioid Visual Guide. Endo Pharmaceuticals. www.endo.com <Accessed January 9, 2012>

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