

# DRUG ALERT

Issued July 2011



Proven Solutions for Cost Containment

Pharmacy

Medical Services  
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Settlement Solutions

## Endocet® Voluntary Recall (10 mg – 325 mg)

### IMPORTANT NOTICE

On June 24, 2011 Endo Pharmaceuticals issued a voluntary recall of two lots of Endocet (oxycodone-acetaminophen) 10 mg-325 mg tablets (100 tablet bottles) with NDC # 60951-712-70 and lot numbers 402415NV and 402426NV. To review the FDA's official recall press release please visit the agency's website at <http://www.fda.gov/Safety/Recalls/ucm260826.htm>.

### BACKGROUND

According to the drug manufacturer, one bottle from each identified lot of Endocet 10 mg – 325 mg tablets was found to contain an unspecified number of Endocet 10 mg-650 mg tablets. Endo Pharmaceuticals indicates that a total of two bottles from lot numbers 402415NV and 402426NV have been found to date containing the incorrectly packaged 10 mg – 650 mg tablets. The affected lots were shipped between April 19, 2011 and May 10, 2011 to wholesalers located in AL, AZ, CA, CO, FL, IL, KY, LA, MO, ND, NC, NH, NJ, NY, OH, PR, PA, and TN. It is possible that wholesalers may have or may be in the process of further distributing these products to pharmacies nationwide. Due to the higher than expected acetaminophen content of the incorrect product, patients may be at an increased risk of exceeding the maximum recommended acetaminophen daily limit of 4,000 mg. Patients who are at the highest risk include those already taking other products that contain acetaminophen, those with existing liver disease or dysfunction, and patients who drink more than three alcoholic beverages per day.

### RECOMMENDED ACTIONS

Endo Pharmaceuticals is currently notifying all pharmacies that may have received the affected products in an effort to facilitate the return of these agents. Patients who may have received prescriptions for affected Endocet products will be contacted by their pharmacists and instructed to dispose of the affected product. Instructions for obtaining a replacement prescription will be provided. PMSI's Mail Order Pharmacy patients will be contacted in a similar fashion.

### 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



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#### REFERENCES

Endo Pharmaceuticals Issues Voluntary, Nationwide Recall of Two Lots of Endocet® (Oxycodone/Acetaminophen, USP) Tablets, 10 MG/ 325 MG. FDA Recalls, Market Withdrawals, & Safety Alerts. <http://www.fda.gov/Safety/Recalls/ucm260826.htm> <Accessed June 27, 2011>

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