

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Hydrocodone Bitartrate and Acetaminophen Tablets,
Phenobarbital Tablets by Qualitest:
Recall – Incorrect Package Labeling**

SOURCE: FDA MedWatch

AUDIENCE: Pharmacy, Patient

ISSUE: An individual bottle of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10mg / 500mg, NDC 0603-3888-20, 60 count was found incorrectly labeled with a Phenobarbital Tablets, USP 32.4 mg, NDC 0603-5166-32, 1000 count label, printed with Lot Number T150G10B. Both products are manufactured by Qualitest Pharmaceuticals.

As a result of this mix-up, patients may unintentionally take Hydrocodone and acetaminophen tablets, instead of the intended dose of Phenobarbital. Unintentional administration of Hydrocodone can lead to serious adverse events including respiratory depression, CNS depression, coma and death, especially in opioid naïve patients and patients on other CNS depressants. Unintentional administration of acetaminophen may result in liver toxicity in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. Additionally, missing doses of Phenobarbital could result in loss of seizure control.

BACKGROUND: The recall includes the following products:

- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10mg / 500mg, NDC 0603-3888-20, 60 count, Lot Numbers T150G10B, T120J10E and T023M10A
- Phenobarbital Tablets, USP 32.4 mg, NDC 0603-5166-32, 1000 count, Lot Numbers T150G10B, T120J10E and T023M10A

Recalled lots were distributed between Sept. 21, 2010 and Dec. 29, 2010 to wholesale and retail pharmacies nationwide (including Puerto Rico).

RECOMMENDATION: Consumers who have affected product should stop using the product and contact Qualitest at 1-800-444-4011 for reimbursement. Lot numbers can be found on the side of the bottle.

Healthcare professionals and patients are encouraged to report adverse events or side

effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the company press release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm242527.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.