catamaran™

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breaking news, drug safety alerts and major events

DRUG RECALL: Qualitest issues a Voluntary, Nationwide Recall of 101 lots of Hydrocodone Bitartrate and Acetaminophen tablets, USP 10 mg/500 mg

On December 6, 2012, Qualitest issued a voluntary, nationwide recall of hydrocodone bitartrate and acetaminophen tablets, USP 10 mg/500 mg because the tablets from the affected lots may exceed the weight requirements and could exceed labeled potency requirements of hydrocodone bitartrate and acetaminophen.

For more information, requests for additional copies, or for questions regarding plan benefit changes, contact your Catamaran Account Manager.

what is the role of Catamaran in this product recall?

- We are informing our clients of a recently announced voluntary, nationwide recall from Qualitest.
- The product affected by this recall is:
  - Hydrocodone Bitartrate and Acetaminophen tablets, USP 10 mg/500 mg.

NDC Number	Bottle Count
0603-3888-16	30
0603-3888-20	60
0603-3888-02	90
0603-3888-21	100
0603-3888-22	120
0603-3888-26	150
0603-3888-04	180
0603-3888-28	500
0603-3888-32	1000

  - All 101 affected lot numbers start with a letter “C” and were distributed between February 20, 2012 and November 19, 2012, to wholesale distributors and retail pharmacies nationwide.
- Catamaran is currently in the process of determining the impact of this recall to our clients by identifying the number of affected members and prescriptions.
- Catamaran is providing a member notification letter template for those clients interested in communicating this recall directly to their members. The letter is intended to inform members of the recall, and it advises them to contact their health care professional with any questions.
- Catamaran is also providing a prescriber notification letter template for those clients interested in communicating this recall directly to recent prescribers. The letter template includes the listing of impacted patients per prescriber.

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overview: Qualitest announces a voluntary, nationwide recall of 101 lots of hydrocodone bitartrate and acetaminophen tablets, USP 10 mg/500 mg due to oversized tablets that may exceed labeled potency of hydrocodone bitartrate and acetaminophen.

- The voluntary recall was initiated due to the possibility that the affected lots may contain tablets that exceed the weight requirement and could exceed the potency requirements for the ingredients of hydrocodone bitartrate and acetaminophen.
- Hydrocodone bitartrate and acetaminophen 10mg/500 mg tablets are indicated for the relief of moderate to moderately severe pain.
- Bottles from the affected lots may contain tablets that have a higher dosage of acetaminophen, and as a result, it is possible that members could take more than the intended acetaminophen dose. Unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen-containing medications, patients with liver dysfunction, or people who consume more than three alcoholic beverages a day. The product label warns consumers that acetaminophen overdose can potentially cause severe liver damage, at times resulting in liver transplant or death.
- Additionally, consumption of acetaminophen from other over-the-counter products should be avoided. Members should contact their health care professional with any questions.
- Consumption of a higher dose of hydrocodone than intended may result in an increase in the severity or frequency of side effects, such as sedation or respiratory depression. Patients at higher risk for increased side effects include the elderly, patients with severe kidney or liver impairment, and patients taking interacting medications that also cause sedation or certain antidepressants.
- The maximum daily dose of hydrocodone bitartrate and acetaminophen 10 mg/500 mg is six tablets per day.
- Qualitest reports that no injuries have been reported to date.
- Hydrocodone bitartrate and acetaminophen tablets are approximately 16.51 mm in length, pink, capsule-shaped tablets, with “3600” debossed on one side of the tablet and “V” on the other side.
- Members who have the affected lots should contact Qualitest at 1-800-444-4011. Members with questions about the Qualitest hydrocodone bitartrate and acetaminophen tablet recall should contact their pharmacy or prescriber for more information.
- Pharmacists and wholesalers are asked to check their inventories for the affected lots, segregate any material from the lots, and to contact MedTurn at 1-800-967-5952 for instructions on product return. Pharmacies that received the affected lots will be contacted directly by Qualitest.
- For more information, contact Qualitest at 1-800-444-4011; Monday through Friday between the hours of 8 AM and 5 PM CST. Reports of adverse reactions or quality problems can also be reported to Qualitest at 1-800-444-4011; Monday through Friday between the hours of 8 AM and 5 PM CST.
- Any adverse events that may be related to the use of Qualitest hydrocodone bitartrate and

acetaminophen tablets should be reported to the FDA's MedWatch Program either online (at www.fda.gov/MedWatch/report.htm), by regular mail (MedWatch, Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-332-0178).

- This voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

references and resources

- FDA Recall: Qualitest Issues Voluntary, Nationwide Recall of 101 Lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg Due to the Potential for Oversized Tablets. December 7, 2012. Available at: http://www.fda.gov/Safety/Recalls/ucm331218.htm?source=govdelivery. Accessed December 7, 2012.

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