



NATIONAL PBM BULLETIN

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DEPARTMENT OF VETERANS AFFAIRS - VETERANS HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
AND CENTER FOR MEDICATION SAFETY PSCI (VA MedSAFE)

**Dispensing of Incorrect Product Due to Change in Formulation of National Vitamin Company
Calcium 500 mg with Vitamin D 200 International Units (IU) to Calcium 500 mg with Vitamin D 400 IU
(NDC 54629-068101) without Notification to the Food and Drug Administration (FDA)**

I. ISSUE

National Vitamin Company changed their formulation of Calcium 500 mg with Vitamin D 200 International Units (IU) to Calcium 500 mg Vitamin D 400 IU, without notifying the FDA or changing the product NDC, leading to the dispensing of the incorrect product.

II. BACKGROUND

VA noted that NDC 54629-068101 is linked to Calcium 500mg Vitamin D 200 IU instead of Calcium 500mg Vitamin D 400 IU as indicated on the labeling of the bottle. VA contacted the manufacturer (National Vitamin Company) who stated that the increase in Vitamin D to 400 IU occurred on or about May 18, 2008, without filing this change in formulation with the FDA. No other changes to the formulation were made. This product is on Federal Supply Schedule V7978-5621X and is McKesson product number 1960731.

III. DISCUSSION

Current (June 2008 to August 2008) VA utilization of Calcium 500mg Vitamin D 400 IU (NDC 54629-068101) shows that the affected product has been dispensed to 41,357 unique patients, with the majority of patients prescribed ≤ 5 tablets per day, corresponding to a daily dose of Vitamin D ≤ 2000 IU. Per the National Institutes of Health (NIH), Office of Dietary Supplements, this daily dose of Vitamin D is within the Institute of Medicine (IOM) recommendations for the Tolerable Upper Intake Level (i.e., maximum daily dose that is unlikely to result in adverse effects) set at 2000 IU per day. In addition, review of safety data with vitamin D [where 25(OH)D levels that correspond with vitamin D intake were available] found reported cases of toxicity to occur at doses of $> 40,000$ IU per day. Therefore, it is felt that the increase in Vitamin D prescribed for the short term should not result in harm to those patients prescribed ≤ 5 tablets per day (equivalent to Vitamin D ≤ 2000 IU per day). However, due to the potential risk for unrecognized hypercalcemia in patients with underlying medical conditions including primary hyperparathyroidism, granulomatous disease, sarcoidosis, or in patients with a history of nephrolithiasis, or those receiving thiazide diuretics, it is recommended that the 234 unique patients prescribed higher doses (≥ 6 tablets per day) be evaluated on an individual patient case basis and in some patients, a serum calcium level may be indicated.

IV. PBM AND VA MEDSAFE RECOMMENDATIONS include:

- Immediately sequester the affected product: National Vitamin Company Calcium 500mg Vitamin D 400 IU (NDC 54629-068101), Federal Supply Schedule V7978-5621X, McKesson product number 1960731.
- Providers should be notified of the change in formulation and that this product will no longer be dispensed, and the correct formulation will be dispensed at the patient's next refill.
- Providers should be notified of their patients who have received the affected product and are inadvertently taking more than 2000 IU Vitamin D per day.
- Providers should evaluate their patients receiving ≥ 6 tablets per day on a case by case basis taking into consideration any underlying medical conditions that may predispose their patient to hypercalcemia; in some patients, a serum calcium level may be warranted.

V. REFERENCES

1. National Institutes of Health, Office of Dietary Supplements. Dietary Supplement Fact Sheet: Vitamin D. Updated Sep 9, 2008. Available at: <http://ods.od.nih.gov/factsheets/vitamind.asp>. Accessed Oct 6, 2008.
2. Vieth R. Vitamin D supplementation, 25-hydroxyvitamin D concentrations, and safety. *Am J Clin Nutr* 1999;69:842-56.