

# Vitamin D3 50,000IU

Product #103

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. The information provided here is intended to help health care professionals make informed decisions about recommending this product safely and effectively.

## Supplement Facts<sup>v1</sup>

Serving Size 1 Capsule  
Servings Per Container 15

1 capsule contains	Amount Per Serving	% Daily Value
Vitamin D3 (as Cholecalciferol)	50,000 IU	12,500%

Other Ingredients: Natural Vegetable Capsules. This product may contain one or more of the following: Calcium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide and Stearic Acid.

### Formula Rationale:

High dose vitamin D3 capsules for loading doses or intermittent high dose therapy.

### Dose:

This product is a high dose vitamin D capsule that is not typically for daily use. Please refer to your physician for a dosing schedule.

## Research Findings:

### Vitamin D:

- Research supporting vitamin D supplementation has increased dramatically over the past decade and has significantly revitalized interest in this important nutrient. While in the past, vitamin D was recognized mainly for its role in bone health, recent epidemiological and randomized-controlled trials have uncovered relationships between low levels of vitamin D and a number of chronic conditions, including muscle pain and weakness, autoimmune diseases such as type 1 diabetes, colorectal cancer, cardiovascular disease, inflammatory bowel disease, and multiple sclerosis. These significant and widespread findings have prompted new controversy in defining "optimal" serum levels of vitamin D, as well as the doses needed to achieve them.
- Many U.S. experts consider 30 ng/mL (75 nmol/L) 25(OH)D to be an optimal of vitamin D, such as Michael Holick, one of the world's leading researchers on vitamin D, who agrees that 30 ng/mL (75 nmol/L) "is required to maximize vitamin D's beneficial effects for health."
- Below is how the Point Institute of Nutraceutical Research defines vitamin D levels:

	ng/mL	nmol/L
<b>Deficiency</b>	10 to 15	25 to 37
<b>Insufficiency</b>	15 to 30	37 to 75
<b>Minimum target</b>	30	75
<b>Therapeutic*</b>	40 to 70	100 to 175
<b>Upper limit</b>	100	250
<b>Excessive</b>	over 100	over 250

The Vitamin D Council recommends a target level of 50-80 ng/mL, year-round.

### Intermittent Dosing:

- A study examining the effects of either no supplementation, low-dose supplementation (1,000 IU/day) or high-dose supplementation (50,000 IU/week) of vitamin D3 in women diagnosed with stage 3 breast cancer, found that weekly high-dose supplementation significantly increased 25OH vitamin D3 levels, while daily low-dose supplementation did not significantly increase levels.<sup>1</sup>

- Regulatory T cells (Tregs), which down regulate the immune system, maintains tolerance to self-antigens, and down regulates autoimmune disease, play an important role in health. A study examining the effects of a high dose of vitamin D3 supplementation (140,000 IU monthly for 3 months) on Tregs, found the percent of Tregs increased significantly in the vitamin D3 group, but remained unchanged in the placebo group.<sup>2</sup>

#### Loading Dose:

- A study was performed examining the effects of three different high dose vitamin D3 regimens on serum blood levels in the elderly. 63 elderly patients were divided into three dosing regimens: a 500,000 IU loading dose; the loading dose plus 50,000 IU/month; or 50,000 IU/month. The loading and the loading+ monthly groups showed increases in 25 OH D of 58 +/-28 nmol/L from baseline to 1 month. Thereafter, levels gradually declined to plateaus of 69 +/-5 nmol/L and 91 +/-4 nmol/L, respectively. In the monthly group, 25 OH D levels reached a plateau of ~80 +/-20 nmol/L at 3-5 months. The study concludes that large loading doses of vitamin D3 rapidly and safely normalize 25OH D levels in the elderly.<sup>3</sup>
- Thirty two women with serum 25(OH)D concentrations = or <10 mcg/L were treated with 50,000 IU of D3 daily for 10 days. At an average time after treatment of 4 months, serum 25(OH)D increased from 8 +/- 1mcg/L to 21 +/-5mcg/L. The study concludes that 50,000 IU per day of D3 for 10 days, provides a simple, safe, and effective way of managing vitamin D deficiency. Its short-term nature may result in higher compliance than daily dosing regimens.<sup>4</sup>
- In a study examining the differences between D2 and D3 absorption in 20 humans over a 28 day period, it was found that a single dose of 50,000 IU of D3 and D2 were both able to produce a similar rise in serum concentration, indicating an equivalent absorption. Both produced similar initial rises in serum 25OH D over the first 3 days, but 25OH D continued to rise in the D3 treated patients, peaking at day 14, whereas serum 25OH D fell rapidly in the D2 treated patients and was not different from baseline at 14 days. The authors concluded that vitamin D2 potency is less than one third that of D3.<sup>5</sup>
- In a double-blind, placebo-controlled pilot study in a medical ICU, twenty-five patients with vitamin D deficiency (25OH D <20ng/ml) were given either 540,000 IU of D3 or placebo. The mean increase in the D3 group was 25 ng/ml. This study shows that a single high dose of D3 corrects vitamin D deficiency within 2 day in most patients without causing adverse effects.<sup>6</sup>
- A study examining the effects of a single dose of 100,000 IU or 200,000 IU of vitamin D3 in patients with type 2 diabetes found systolic blood pressure was significantly lower in both treatment arms than in the placebo group at 8 weeks.<sup>7</sup>

#### Contraindication, Adverse or Other Reactions:

Class 2. If you are pregnant or nursing, consult your physician before taking this product.

#### References:

1. Peppone LJ, Huston AJ, Reid ME, et al. The effect of various vitamin D supplementation regimens in breast cancer patients. *Breast Cancer Res Treat.* May 2011;127(1):171-177.
2. Bock G, Prietl B, Mader JK, et al. The effect of vitamin D supplementation on peripheral regulatory T cells and beta cell function in healthy humans: a randomized controlled trial. *Diabetes Metab Res Rev.* Nov 2011;27(8):942-945.
3. Bacon CJ, Gamble GD, Horne AM, Scott MA, Reid IR. High-dose oral vitamin D3 supplementation in the elderly. *Osteoporos Int.* Aug 2009;20(8):1407-1415.
4. Wu F, Staykova T, Horne A, et al. Efficacy of an oral, 10-day course of high-dose calciferol in correcting vitamin D deficiency. *N Z Med J.* Aug 8 2003;116(1179):U536.
5. Armas LA, Hollis BW, Heaney RP. Vitamin D2 is much less effective than vitamin D3 in humans. *J Clin Endocrinol Metab.* Nov 2004;89(11):5387-5391.
6. Amrein K, Sourij H, Wagner G, et al. Short-term effects of high-dose oral vitamin D3 in critically ill vitamin D deficient patients: a randomized, double-blind, placebo-controlled pilot study. *Crit Care.* 2011;15(2):R104.
7. Witham MD, Dove FJ, Dryburgh M, Sugden JA, Morris AD, Struthers AD. The effect of different doses of vitamin D(3) on markers of vascular health in patients with type 2 diabetes: a randomised controlled trial. *Diabetologia.* Oct 2010;53(10):2112-2119.

