Product #103

Vitamin D3 50,000IU

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:

<table>
<thead>
<tr>
<th>Deficiency</th>
<th>10 to 15</th>
<th>25 to 37</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficiency</td>
<td>15 to 30</td>
<td>37 to 75</td>
</tr>
<tr>
<td>Minimum target</td>
<td>30</td>
<td>75</td>
</tr>
<tr>
<td>Therapeutic*</td>
<td>40 to 70</td>
<td>100 to 175</td>
</tr>
<tr>
<td>Upper limit</td>
<td>100</td>
<td>250</td>
</tr>
<tr>
<td>Excessive</td>
<td>over 100</td>
<td>over 250</td>
</tr>
</tbody>
</table>

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.\(^1\)
• Regulatory T cells (Tregs), which down regulate the immune system, maintain tolerance to self-antigens, and downregulate 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.2

**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 OHD 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 OHD 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 25OHD levels in the elderly.3

• 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 +/-1 mcg/L to 21 +/-5 mcg/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 shortterm nature may result in higher compliance than daily dosing regimens.4

• 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 25OHD over the first 3 days, but 25OHD continued to rise in the D3 treated patients, peaking at day 14, whereas serum 25OHD 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 D3.5

• In a double-blind, placebo-controlled pilot study in a medical ICU, twenty-five patients with vitamin D deficiency (25OHD <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.6

• 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.7

Contraindication, Adverse or Other Reactions:
Class 2: If you are pregnant or nursing, consult your physician before taking this product.

References: