Dietary Supplement Information for Physicians with Naturokinetics®

PRODUCT CODE: P0377

CATEGORY: VITAMINS A, D, E & K

# Vitamin D<sub>3</sub> 50,000 IU

#### **TECHNICAL SUMMARY**

The major biologic function of vitamin D is to maintain healthy blood levels of calcium and phosphorus.\* Vitamin D supports bone health by promoting calcium absorption and bone mineralization.\* Vitamin D also plays an important role in immune function and helps to regulate cell growth and differentiation.\*

# Structure Formula:

**Chemical Name:** Cholecalciferol (activated 7-dehydrocholesterol;  $(3\beta,5Z,7E)$ - 9,10-secocholesta-5,7,10(19)-trien-3-ol).

Allergen and Additive Disclosure: Not manufactured with yeast, wheat, gluten, soy, corn, milk, egg, fish, shellfish or sesame ingredients. Produced in a GMP facility that processes other ingredients containing these allergens.

Delivery Form: Softgels.

# **ROLE AS NUTRIENT/FUNCTION**

The function of vitamin  $D_3$  in the body is well established; it allows for the tight regulation of calcium levels in the blood, as well as phosphate homeostasis.\* In addition, more recent discoveries have shown that vitamin D is also involved in many other bodily functions such as regulation of cell proliferation, cell differentiation, immunomodulation, and cardiovascular health.\*

#### **NATUROKINETICS®**

**Liberation:** Dissolution of the softgel capsule is measured in water using a USP testing method with dissolution between zero and 60 minutes.

**Absorption:** Vitamin  $D_3$  is a fat-soluble vitamin. It is absorbed with dietary fats in the small intestine, enters the blood circulation via the lymphatic system, and is transported in the chylomicron fraction of plasma. It is recommended that Vitamin  $D_3$  supplements be consumed with a fat-containing meal to maximize efficiency of absorption.

**Distribution**: Once vitamin  $D_3$  enters the bloodstream it is cleared by the liver or is rapidly stored in fat tissue. Vitamin  $D_3$  deposited in fat is not readily available to exert its bodily functions. Continuous, long-term ingestion of high doses of vitamin  $D_3$  results in proportional increase in blood levels in most individuals, reaching a plateau after about 6 weeks of supplementation. (Figure 1)

# **Supplement Facts**

Serving Size 1 Softgel

Amount Per Serving % Daily Value

Vitamin D<sub>3</sub> 1,250 mcg (50,000 IU) 6250% (as Cholecalciferol) (from Lanolin)

Other ingredients: Organic Extra Virgin Olive Oil, Softgel Capsule [bovine gelatin (BSE-free), glycerin, water] and Safflower Oil.

- Helps Maintain Strong Bones\*
- Supports Immune System\*

**SUGGESTED USAGE:** Take 1 softgel with a fat-containing meal as directed by your healthcare practitioner (typically once per week). **This product is intended to be used under the supervision of a healthcare professional and not for daily use.** Vitamin D and calcium levels should be monitored while taking this product. Do not exceed recommended dose

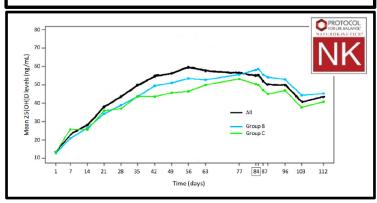


Figure 1: Serum 25(OH)D levels in healthy participants receiving 50,000 IU weekly (group B), or 100,000 IU biweekly (group C) vitamin D3 supplementation for 84 days.

**Metabolism:** Vitamin  $D_3$  (cholecalciferol) is an inactive provitamin and must first be metabolized to its active form before it can function. This metabolism is complex with a first phase occurring in the liver and a second phase in the kidney. It is tightly regulated by the parathyroid gland, which is sensitive to changes in blood calcium and phosphate levels.

**Elimination:** The products of vitamin D<sub>3</sub> metabolism are excreted via the bile into the feces, and very little is eliminated through the urine.

# **CLINICAL VALIDATION**

## **Bone Health Support\***

In a randomized, placebo-controlled study with women aged >49 years
who were vitamin D deficient, vitamin D<sub>3</sub> supplementation (4,000
IU/day for 6 months), without changing calcium intake, resulted in
statistically significant improvement in the markers of bone turnover
(osteocalcin and C-telopeptide) as compared to placebo.\*

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## Immune System Support\*

• In a large epidemiological study in which data from 45-year-old adults living in the UK were analyzed, the rate of respiratory events relative to strong seasonal pattern had an inverse relationship to the pattern for 25(OH)D concentrations. After adjustment for adiposity, lifestyle, and socio-economic factors, each 4 ng/mL (10 nmol/l) increase in 25(OH)D was associated with a 7% lower risk of a respiratory event (Figure 2).\*

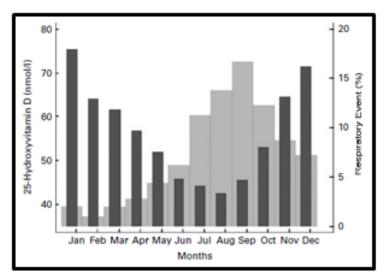


Figure 2: Geometric mean of 25-hydroxyvitamin D (nmol/l,) concentrations and the prevalence of respiratory events in the 1958 British birth cohort.

• In a randomized study on schoolchildren between January and March, the subjects were treated with supplemental vitamin D and analyzed for respiratory health using two groups. Respiratory health was compared between the control group and the supplemental group for the 3-month period of the study (Figure 3). The results showed the maintenance of respiratory health within the supplemental group, which suggests that supplemental vitamin D<sub>3</sub> can help support immune system functioning particularly in responds to seasonal challenges.\*

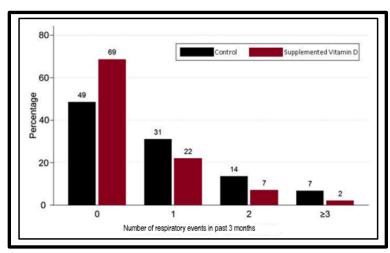


Figure 3: Number of respiratory events during the three month period in the supplementation and control groups.

# **SAFETY INFORMATION**

**Tolerability:** Oral supplementation of vitamin D<sub>3</sub> is typically well tolerated. **This product is not intended for daily use;** however some publications suggest that some individuals taking up to 60,000 IU/d vitamin D for more than a year did not develop hypercalcemia. If this product is accidentally taken daily without medical supervision, it should be stopped and calcemiał surveillance is recommended for several weeks as vitamin D has a long half-life. Vitamin D supplementation can be resumed once serum calcium is confirmed as normal and blood level of 25(OH) vitamin D are below 125 nmol/L. (IOM‡ established in 2011 that 25(OH) vitamin D levels above 125-150 nmol/L should be avoided)

**Contraindications:** Vitamin D<sub>3</sub> should be used cautiously by those taking cardiac glycosides and anyone with hypercalcemia.

# **INTERACTIONS**

**Drug Interactions:** Possible interactions with cardiac glycosides, atorvastatin, and thiazide diuretics.

**Supplement Interactions:** Vitamin D increases calcium and magnesium absorption and may therefore interact with calcium and magnesium supplementation.

Interaction with Lab Tests: None known.

#### **STORAGE**

Store in a cool, dry place.

<sup>t</sup>Calcemia: measure of calcium levels in blood.

<sup>‡</sup>IOM: Institute of Medicine