



Vitamin D, Part II: Perspectives on Toxicity

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Vitamin D has traditionally been associated with its role as an essential nutrient for optimal bone mineralization and the maintenance

of a healthy skeleton¹⁻³. However, mounting evidence implicates Vitamin D in the involvement of numerous physiological functions, including regulation of immune function and balanced inflammatory responses⁴⁻¹⁰, the secretion of insulin by pancreatic β -cells⁷⁻¹⁴, a number of brain activities^{15,16}, heart function^{17,18} and blood pressure regulation^{17,19}, as well as cell cycle regulation^{20,21}.*

Our improved understanding of Vitamin D's functions has led to not only a marked increase in Vitamin D research, but also in a renewed concern surrounding its toxicity. As with any biologically active agent, doses sufficiently high enough can produce toxic effects. The published evidence has shown that serum concentrations greater than 500 nmol/L (200 ng/mL) can produce hypercalcemia, the toxic consequence of Vitamin D excess. Indeed, hypercalcemia can be fatal through neuromuscular impairment, polyuria, and ensuing dehydration. But how much Vitamin D can be consumed before reaching this threshold level? A look at Vitamin D through the context of sunlight exposure should provide some perspective.

First, let us consider that human beings evolved in a tropical environment with almost full body exposure to sunshine on most days year round. The safety of solar-derived Vitamin D is well-accepted and documentation of Vitamin D toxicity due to UV exposure is non-existent. Therefore, humans must have developed some built-in mechanism that prevents sunlight-induced toxicity.

There appears to be a physiological limit for serum 25(OH)D concentration that can be achieved through UV exposure of approximately 220 nmol/L (88 ng/mL)²². This is due to a number of factors: 1) the skin is limited in its capacity for Vitamin D production by the supply of its precursor,

7-dehydrocholesterol^{23,2} the concentration of pre-vitamin D reaches a maximum value after a relatively short UV exposure and further UV exposure results only in more extensive conversion of the pre-vitamin to inactive metabolites^{24,3} photosynthesis decreases with repeated sun exposure^{24,4} the average whole-body half-life for vitamin D molecules is only about 2 months²⁸. Therefore, a logical corollary would be that this maximum serum level of 220 nmol/L is not only safe, but might reasonably be considered to be optimal.

Abundant sun exposure by modern standards can result in serum 25(OH)D levels of 150 nmol/L (60 ng/mL). This level also reflects an oral intake of >7600 IU/day by men during winter months with little sun exposure^{26,27}. This represents a level that is below the physiological limit of 25(OH)D production, and substantially less than serum levels that produce hypercalcemia (500 nmol/L, or 200 ng/mL)²⁵. In fact, clinical studies indicate that 10,000 IU/day supplemental Vitamin D during winter months may be what it takes to reach serum levels of 220 nmol/L^{25,27}.

Serum responses to supplemental Vitamin D are dependent, of course, on individual health status, age, and lifestyle variations. It is interesting to note that most clinical toxicity studies have been conducted on male subjects. It is important to recognize, however, that studies involving high doses in both men and women have demonstrated no sex-specific difference with respect to safety²⁵.

In fact, men tend to achieve a higher Vitamin D status than women in general, presumably due to differences in adiposity and BMI. Given the potential for inter-individual variation therefore, monitoring of serum levels via laboratory tests is advised when supplementing with relatively high doses of this nutrient.

The toxicity of oral Vitamin D₃ has been thoroughly reviewed by Hathcock, et al., 2007²⁵. This review looks at 21 clinical studies on oral Vitamin D that took place between 1980 and 2006, using doses of up to 100,000 IU per day. In these studies, even very high doses (40,000-50,000 IU per day) did not produce toxicity, even after months of treatment. The established potential of the toxicity of oral Vitamin D if taken in sufficiently excessive doses (>100,000 IU per day) has led to overly cautious recommendations for this nutrient. With the improved knowledge of its safety, supported by more than adequate clinical data, you now have safety information that will allow you to determine the appropriate doses for your patients.

Protocol For Life Balance™ offers Vitamin D₃ products in a range of doses: 1000 IU, 2000 IU, 5000 IU and 10,000 IU (new this month). In addition, our Liquid Vitamin D can be used to tailor doses to individual patients.

*For References, please visit www.protocolforlife.com
Amy Kosowski, MS, LDN, Amy Kosowski is a Protocol for Life Balance™ scientist.*



New!



Vitamin D₃ 10,000 IU Cholecalciferol

Ongoing clinical studies continue to demonstrate the system-wide beneficial effects associated with high-dose vitamin D₃ (cholecalciferol) therapy. With more patients deliberately avoiding UV exposure and whole milk, supplementation has seen steady increases in demand and user success rates.

Protocol For Life Balance Vitamin D-3 10,000IU has as a base the probiotic enhancer, Nutra Flora FOS®. Nutra Flora FOS® is a concentrated source of fructooligosaccharides (FOS), a non-digestible carbohydrate which aids the growth of beneficial bacteria such as bifidus and acidophilus.*

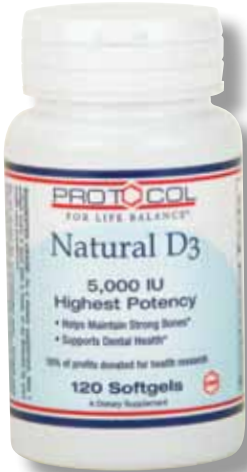
Protocol for Life Balance™ Vitamin D-3 10,000 IU offers unparalleled potency and exceptional value for both you and your patients.

Supplement Facts

Serving Size: 1 Vcap®
Servings Per Container: 90

Amount Per Serving	
Vitamin D ₃ (as Cholecalciferol) (from Lanolin)	10,000 IU

Other ingredients: **NutraFlora® FOS (Fructooligosaccharides)**, Cellulose (capsule) and Stearic Acid (vegetable source).



Vitamin D₃ 2,000 IU & 5,000 IU

Vitamin D₃ softgels supply this key vitamin in a highly absorbable liquid softgel form. Vitamin D is normally obtained from the diet or produced by the skin from the ultraviolet energy of the sun. However it is not abundant in food. As more people avoid sun exposure, Vitamin D supplementation becomes even more necessary to ensure that your body receives an adequate supply.

- *Small, Easy To Swallow Softgel*
- *Supports Dental Health**
- *Helps Maintain Strong Bones**

Supplement Facts

Serving Size: 1 Softgel
Servings Per Container: 120

Amount Per Serving	
Vitamin D ₃ (as Cholecalciferol) (from Lanolin)	5,000 IU

Other ingredients: Olive Oil and Softgel Capsule (gelatin, glycerin, water).



NAC N-Acetyl Cysteine 600 mg with Selenium & Molybdenum

N-Acetyl Cysteine (NAC) is a stable form of the non-essential amino acid L-Cysteine. It is a sulfur-containing amino acid that acts as a stabilizer for the formation of protein structures, and is also necessary for the formation of glutathione.* Molybdenum and Selenium are essential trace minerals that facilitate the production of several important enzymes.* N-acetyl-cysteine (NAC) comes from the sulfur-containing amino acid cysteine, and makes up part of the tripeptide glutathione. Glutathione, along with NAC, are powerful antioxidants. Antioxidants neutralize free radicals, which may damage the body's cells. NAC supplementation can help to increase levels of glutathione in the body.* This unique formula also contains Molybdenum, an essential trace element that functions as a cofactor in many biochemical reactions, and Selenium, another trace mineral that supports glutathione production.*

Supplement Facts

Serving Size 1 Capsule
Servings Per Container: 100

Amount Per Serving	
Molybdenum (as Amino Acid Chelate)	50 mcg
Selenium (as L-Selenomethionine)	25 mcg
N-Acetyl Cysteine	600 mg

Other ingredients: Gelatin (capsule), Stearic Acid (vegetable source) and Citric Acid.

Contains no sugar, salt, starch, yeast, wheat, gluten, corn, soy, milk, egg, shellfish or preservatives.

phone: 877.776.8610
fax: 800.886.1045

Code	Products	Size	Profes.	Retail	Qty.
P0105	5-HTP 100 mg	90 Vcaps®			
P0108	5-HTP 200 mg + Tyrosine	60 Vcaps®			
P1811	A - Biotic™ Enteric Coated, Potent	60 Gels			
P0076	Acetyl-L-Carnitine 500	100 Vcaps®			
P3344	Adrenal Cortisol Support™	90 Vcaps®			
P3032	AHCC® 500 mg	60 Vcaps®			
P3282	Aller-All™ Seasonal Support	60 Tabs			
P3036	Aloe Vera 5,000	100 Gel			
P3042	Alpha Lipoic Acid 250 mg	90 Vcaps®			
P3046	Alpha Lipoic Acid 600 mg Plus	60 Vcaps®			
P0030	L-Arginine 500 mg	180 Caps			
P2958	BioCore® Enhanced Enzymes	90 Vcaps®			
P0471	Biotin 5000 mcg	90 Vcaps®			
P1228	Bone Strength™	180 Caps			
P1720	Borage/GLA 1050 mg	60 Gels			
P3303	Brain Regain™	60 Vcaps®			
P3063	Brocco Immune™	60 Vcaps®			
P2943	Bromelain 2400 gdu/500 mg	90 Vcaps®			
P3308	C.Away™	90 Vcaps®			
P1268	Cal-Mag, Liquid, Lemon	16 oz			
P1675	CardioTri-Plex™	120 Gels			
P0072	L-Carnitine 500 mg Carnipure®	60 Caps			
P3019	Celadrin® Joint Liposome Lotion	4 oz			
P9470	Protocol Celadrin® Tabletop Display	12 Bottles			
P1415	ChromeMate® 200 mcg	90 Caps			
P1731	CLA Away™	90 Gels			
P0405	CoEnzyme B Complex	60 Tabs			
P3163	CoQ10 60 mg + Fish Oils	90 Gels			
P3208	CoQ10 100 mg Softgels	90 Gels			
P3196	CoQ10 200 mg Lozenges	60 Loz			
P3198	CoQ10 400 mg Softgels	60 Gels			
P3182	CoQ10 600 mg Softgels	60 Gels			
P3186	CoQ10 Liquid 100 mg/tsp	4 oz			
P4638	Curcumin 665 mg 95% Extract	60 Vcaps®			
P3121	D-Flame™ Cox-2 Formula	90 Vcaps®			
P2956	Dairy Digestion™	90 Vcaps®			
P4704	EGCg 400 mg/50%	90 Vcaps®			
P2963	Enzymes-HCl™	120 Caps			
P5993	Fiber O-3™	16 oz			
P1770	Flax Seed Oil 1000 mg Organic	120 Gels			
P0498	Flush Free Niacin 500 mg	90 Vcaps®			
P4683	Ginkgo Biloba 120 mg/24% Plus	100 Vcaps®			
P3318	Glucose Balance™	90 Caps			
P3170	Gluc/Chond/MSM Caps	90 Caps			
P3172	Gluc/Chond/MSM Caps	180 Caps			
P3243	Gluc/Chond 2 per day, Extra Strength	120 Tab			
P3130	Gluc & MSM, Vegetarian 1000 mg	120 Vcaps®			
P3175	Liquid Glucosamine, Chond, MSM	16 oz			
P0094	L-Glutamine 1000 mg	120 Caps			
P3274	Grape Seed OPC 250 mg Extract	90 Vcaps®			
P3055	Immune Renew™ (Org. Mushrooms)	90 Vcaps®			
P3134	Joint-UC™ Collagen	60 Vcaps®			
P1625	Krill Oil, Neptune (NKO®) 500 mg	60 Gels			
P2448	Liver Detox™	90 Caps			
P3062	LYC-O-MATO® 20 mg Lycopene	60 Gels			
P2811	D-Mannose Urinary 500 mg	90 Caps			
P3258	Melatonin 3 mg Lozenge & B-6	120 Loz			
P3326	MetaboEnergetics™	90 Caps			
P0495	Methyl B-12 1,000 mcg	100 Loz			
P0496	Methyl B-12 5,000 mcg	60 Loz			
P4739	Milk Thistle 300 mg/80% Plus	90 Vcaps®			
P2120	MSM 1,000 mg	180 Caps			
P0085	NAC N-acetyl cysteine 600 mg + Antioxidants	100 Caps			
P3140	Nattokinase 100 mg/2000 FU units	60 Vcaps®			
P0453	Nutri-Dose™ B-12 10,000 mcg NEW!	12: 15 mL			

Code	Products	Size	Profes.	Retail	Qty.
P3301	Ocu Support™ Clinical Strength	90 Caps			
P1659	Omega-3 Lemon Liquid /Molecularly Distilled	7 oz			
P1656	Omega-3/Enter 180/120 /Molecularly Distilled	90 Gels			
P1657	Omega-3/Enter 180/120 /Molecularly Distilled	180 Gels			
P1661	Ultra Omega-3 500/250/Molecularly Distilled	90 Gels			
P1661	Ultra Omega-3 500/250/Molecularly Distilled	180 Gels			
P3281	Ortho Detox™	90 Caps			
P2912	Ortho Dophilus™ 8 Strains, 4 Billion	60 Vcaps®			
P0950	Ortho-E™ NON-GE	60 Gels			
P3772	Ortho Liquid Multi™ - Iron Free/Xylitol	16 oz			
P3788	Ortho Multi™ Greens	180 Vcaps®			
P3878	Ortho Multi™ for Men Caps	90 Vcaps®			
P3875	Ortho Multi™ for Men Tabs	90 Tabs			
P3816	Ortho Multi™ Softgel w/ Flax 400 mg	90 Gels			
P3798	Ortho Multi™ for Women Caps	120 Vcaps®			
P3796	Ortho Multi™ for Women Tabs	90 Tabs			
P3340	Ortho Prostate™	90 Gels			
P3368	Ortho Thyroid™	90 Vcaps®			
P1413	OsteoBoron® 3 mg, Natural Form/base	90 Vcaps®			
P0487	Pantethine 300 mg Co-enzyme A	60 Gels			
P4727	Peppermint Oil G.I.™ Enteric	90 Gels			
P3345	PepZin G.I.® Soothe™	60 Tabs			
P2385	Phosphatidyl Serine 100 mg & Ginkgo 60 mg	60 Gels			
P3338	Progesterone Cream Pump - 20 mg	3 oz			
P5955	ProtoClear™ Berry Flavor	2.3 lbs			
P5956	ProtoClear™ Info Card & Sample - Berry	25 g			
P5957	ProtoClear™ Orange Flavor	2.3 lbs			
P5958	ProtoClear™ Info Card & Sample - Orange	25 g			
P5960	ProtoClear™ Vanilla Flavor	2.3 lbs			
P5961	ProtoClear™ Info Card & Sample - Vanilla	25 g			
8931	ProtoClear™ Premium Shaker Cup	12 oz			
P0716	ProtoSorb™ C 500	100 Vcaps®			
P0726	ProtoSorb™ C 1000	100 Tabs			
P2928	ProtoDophilus™ 50 Billion/Cap	50 Vcaps®			
P3321	Red Yeast & CoQ10 30 mg, ALA	90 Vcaps®			
P3500	Red Yeast Rice Extract 600	90 Vcaps®			
P3353	Resveratrol 200 mg Extra Strength	60 Vcaps®			
P2147	D-Ribose Powder	300 g			
P0138	SAMe 200 mg Enteric + B Complex	60 Tabs			
P4756	Saw Prostetio™ 320 mg/85-95% Extract	90 Gels			
P1485	Selenium 200 mcg, Yeast-Free	90 Vcaps®			
P2954	Serrazimes® 33 mg/20,000 units	90 Vcaps®			
P1905	Slimaluma® Plus	60 Vcaps®			
P6957	Stevia Complete Packets	100/box			
P6955	Stevia Non-Bitter Liquid, Sweet	2 fl oz			
P6960	Stevia Non-Bitter Powder, Sweet	1 oz			
P3507	Syrinol® Cholesterol Formula	60 Vcaps®			
P0142	Taurine 1000 mg Caps	100 Caps			
P3145	Ubiquinol CoQH-CF™ 50 mg	60 Gels			
P3380	True Balance™ Multi	120 Caps			
P0166	L-Tryptophan 500 mg	60 Vcaps®			
P0167	L-Tryptophan 500 mg	120 Vcaps®			
P0169	L-Tryptophan 1000 mg	60 Tabs			
P3123	Vein Integrity™ with Trunorin®	90 Vcaps®			
P2168	Virility For Men with LJ100®	60 Vcaps®			
P0452	Vitamin B-12 Liquid Tri-Formula 5,000 mcg	4 oz			
P0690	Vitamin C-1000 Cap+100 Bioflavonoids	120 Caps			
P0365	Vitamin D-3 1,000 IU	120 Gels			
P0367	Vitamin D-3 2,000 IU	120 Gels			
P0372	Vitamin D-3 5000 IU	120 Gels			
P0370	Vitamin D-3, Liquid 5000 IU	2 oz			
P0374	Vitamin D-3 10,000 IU NEW!	90 Vcaps®			
P0906	Vitamin E-400 20% Mixed + Selenium	120 Gels			
P1554	Zinc Glycinate, 30 mg Softgels	120 Gels			



Our Mission: Healthy Patients, Satisfied Physicians

New!

Nutri-Dose™ B-12 10,000 mcg Shots



B Vitamins are essential components in most major metabolic reactions as they play an important role in energy production, including the metabolism of lipids, carbohydrates, and proteins. Vitamin B-12 facilitates energy production and is required for nucleic acid (DNA) synthesis, methionine synthesis from cysteine, and normal myelin synthesis in the nervous system. Along with vitamin B₆ and folic acid, adequate levels of vitamin B-12 are required to maintain healthy plasma homocysteine levels.

The elderly and strict vegetarians are often at risk for Vitamin B-12 deficiency, either due to low dietary intake or decreased absorption. B-12 10,000 mcg Nutri-Dose™ is a convenient and palatable liquid formulation that is absorbed quickly by the body, delivering rapid, energizing nutrition.*

- * Convenient Vial Delivery System / * With Complete Liquid B-Complex
- * Mixed Berry Flavor / * A Dietary Supplement / * Vegetarian Formula

Supplement Facts

Serving Size 1 Tube (15 mL)
Servings Per Container 12

	Amount Per Serving
Calories	50
Total Carbohydrate	13 g
Sugars	3 g
Sugar Alcohol (as Xylitol)	2.5 g
Vitamin C (as Ascorbic Acid)	100 mg
Vitamin B ₁ (from Thiamine HCl)	3 mg
Riboflavin (Vitamin B-2)	3.4 mg
Niacin (as Niacinamide) (Vitamin B-3)	50 mg
Vitamin B ₆ (from Pyridoxine HCl)	10 mg
Folic Acid	400 mcg
Vitamin B₁₂ (as Cyanocobalamin)	10 mg (10,000 mcg)
Biotin	300 mcg
Pantothenic Acid (from Calcium Pantothenate)	50 mg
Choline (from Choline Bitartrate)	5 mg
Inositol	5 mg

Other ingredients: De-ionized Water, Vegetable Glycerine, Fructose, Xylitol, Natural Berry and Cherry Flavors, Malic Acid, Potassium Sorbate (as preservative) and Natural French Vanilla Flavor.

Contains no salt, yeast, wheat, gluten, soy, milk, egg or shellfish. Vegetarian/Vegan Product.

SUGGESTED USAGE: Shake plastic tube before using. Snap top off of tube and squeeze liquid contents into mouth and swallow. Take 1 tube daily, preferably in the morning. Please recycle plastic tube.

*These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease.

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