

Interactions between Drugs and Dietary Supplements

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A recent publication in the American Journal of Medicine (Potential for Interactions Between Dietary Supplements and Prescription Medications, Sood, A., et al, AJM 121 (3), March 2008) looks at clinically significant interactions as a result of concurrent use of dietary supplements and drugs. The authors of this study conducted a cross-sectional, point of care survey at 6 different specialty clinics at the Mayo Clinic, and combined this survey with a review of patient medical records. They used an on-line interaction program to assess the potential clinical significance of each interaction.

In this study, 1818 patients (98.7% response rate) were studied where 710 (39.6%) reported dietary supplement use, but only 26% of medical records contained documented use. Out of these, 107 interactions with potential clinical significance were reported. The 5 most common natural products with a potential for interaction were: **Garlic, Valerian, Kava, Gingko, and St John's Wort.**

These 5 natural products accounted for 68% of the interactions. Protocol For Life Balance™ carries only Gingko in Gingko Biloba 120 mg (item P4683) and Phosphatidyl Serine 100 mg (P2385), and as a minor ingredient in Brain Regain™ (item P3303), Ortho Multi™ for Men (P3875, P3878) and in Ocu Support™ (item P3301)

In the reported study, the 4 most common classes of drugs with interaction potential were: **Antithrombotic medications, Sedatives, Antidepressant agents, and Antidiabetic agents.**

These 4 classes accounted for 94% of the interactions. The authors concluded that (a) only a small number of prescription drugs actually accounted for most of the interactions, and that (b) the actual potential for harm was low. This last point was emphasized by the authors – although a potential for harm existed, no serious adverse response cases were documented.

This study is consistent with our own experiences with dietary supplements. Since 2003 we have maintained accurate records on all adverse events associated with our supplements. With the hundreds of millions of supplements sold by our company during this period, only a handful of serious adverse events have ever been identified, and not all of these had to do with interactions with drugs. Our experience is that those adverse events associated with drugs were mostly due to the side effects of the pharmaceutical. That's why you'll notice the title of this review is "Interactions between drugs and dietary supplements", attempting to rebuff the common misperception that it is the dietary supplement that is the primary instigator.

By the way, at Protocol for Life Balance™ we are in compliance with the new Serious Adverse Event Law, which came into effect at the end of 2007. This law requires us to investigate and report all serious events to the FDA within 15 days of notification. So far this year, no Protocol for Life Balance™ serious adverse event has been reported.

Talking about labels, a unique feature of the Protocol For Life Balance™ labels, and a unique service to you and your patients, is the Cautions and Interactions section on the back side of almost every label in our line-up. Here you will find unbiased, accurate, investigated summaries of scientific and clinical reports on interactions between drugs and the product ingredients, and additional cautions to be considered. Our researchers spent hours and hours gathering this information for your use. Our Medical and Scientific Advisory Board (you can see the members listed in our Product catalog and on our website www.protocolforlife.com) have specifically reviewed the safety of many of our products and have provided input into the caution and interactions.

As an example, see the Cautions and Interaction sections for our new ProtoClear™ products.

Interactions between dietary supplements and drugs are limited to only a few dietary supplements and a few drugs. Their potential for serious harm has also been observed to be limited. Nevertheless, knowing them and dealing with them, is an important function of the practitioner. Through the Protocol for Life Balance™ scientific services, we provide this information to you, in our Product Catalog, on our website www.protocolforlife.com, and on almost every product label. In this way we keep you informed about possible interactions between drugs and dietary supplements, and other cautionary information. You are then equipped to practice health and wellness with the most advanced knowledge in your field.



Indications and Cautions:

If you have sensitivity to any ingredients, please check with your healthcare practitioner.

Milk Thistle may affect the liver's metabolism of alcohol, acetaminophen, butyrophenones (such as haloperidol), phenothiazines (such as chlorpromazine, fluphenazine and promethazine), phenytoin, halothane, disipain and cyclosporine.

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September - October 2008

NEW! ProtoClear™

Available in Natural Berry and Orange Flavor

Why ProtoClear™

ProtoClear™ is a unique formula manufactured in a state-of-the-art, GMP-certified facility by Protocol For Life Balance™, a provider of physician grade quality dietary supplements. Unlike many companies that do not have the resources to manufacture their own products, our company has been manufacturing dietary products for over 40 years and employs some of the most stringent Quality Control/Quality Assurance standards in the natural products industry.

ProtoClear™ contains only the highest quality ingredients. Each one has been specifically included based on studies that have demonstrated its role in detoxification and nutritional support*. Each ingredient undergoes extensive testing and lot-specific acceptance before testing and use in our products.

ProtoClear™ mixes well, tastes great and is not grainy or chalky. It is very easy to use both at home and away.

ProtoClear™ is a non-genetically engineered (non-GE, non-GMO) brown rice protein isolate with added vitamins, minerals, antioxidants, amino acids, botanicals, organic golden flax meal, modified citrus pectin (PectaSol®), and enzyme-enhanced natural Stevia extract. Non-GE brown rice protein was chosen as the base of this formulation because it is unusual for people to be sensitive to rice protein.

ProtoClear™ is free of soy protein, wheat, gluten, casein, dairy, corn protein, refined sugar, tree nuts, peanuts, and caffeine and is produced in a peanut-free processing facility using GMP standards of sanitation to avoid cross contamination.

What to Expect with ProtoClear™

The ProtoClear™ formula is a pleasant-tasting powdered drink mix that can easily be added into water, juice, or other preferred liquid. The ingredients in the ProtoClear™ mix have been carefully selected based on their ability to support the body during cleansing and detoxification*. It contains a perfectly balanced mix of protein, carbohydrates, electrolytes, vitamins, minerals, antioxidants, amino acids, and herbal extracts. Working together within the body, this unique formulation can help eliminate toxins, protect and nourish cells, and provide the constituents needed for optimal health*. ProtoClear™ was developed not only to detoxify the cells, but also to serve as a nutritional complement to the dietary and exercise portions of the program*.

Supplement Facts		
Serving Size (55 g)	Servings Per Container 21	
	Amount Per Serving	% Daily Value
Calories	210	
Calories from Fat	20	
Total Fat	2 g	3%*
Saturated Fat	0.5 g	3%*
Trans Fat	0 g	†
Cholesterol	0 mg	0%
Total Carbohydrate	20 g	7%*
Dietary Fiber	3 g	12%*
Sugars	5 g	†
Protein	26 g	52%*
Beta-Carotene (as pro-Vitamin A 2.4 mg)	4,000 IU	80%
Vitamin A (from Retinyl Palmitate)	1,000 IU	20%
Vitamin C (ProtoSorb™C)	300 mg	500%
(from Threonic Acid Enhanced Buffered Calcium Ascorbate)		
Vitamin D3 (as Cholecalciferol)	200 IU	50%
Vitamin E (from d-alpha Tocopherol Succinate)	50 IU	167%
Vitamin B1 (from Cocarboxylase)**	2 mg	133%
Riboflavin (from Riboflavin-5-Phosphate Sodium)**	2 mg	118%
Vitamin B3 (from NAD)	10 mg	50%
(as Nicotinamide Adenine Dinucleotide)**		
Vitamin B6 (from P-5-P Monohydrate)	3.4 mg	170%
(Pyridoxal-5-Phosphate)**		
Folate (as Folic Acid)	200 mcg	50%
Vitamin B12 (as Methylcobalamin)**	25 mcg	417%
Biotin (as d-Biotin)	150 mcg	50%
Pantothenic Acid (from Calcium d-Pantothenate)	20 mg	200%
Calcium	200 mg	20%
(from Calcium Citrate and Buffered Calcium Ascorbate)		
Iodine (from Potassium Iodide)	50 mcg	33%
Magnesium (from Magnesium Citrate)	200 mg	50%
Zinc (from Zinc Picolinate)	10 mg	67%
Selenium (from L-Selenomethionine)	35 mcg	50%
Copper	500 mcg	25%
(from Copper Glycinate Chelate) (TRAACS®) (Albion)		
Manganese	500 mcg	25%
(from Manganese Glycinate Chelate) (TRAACS®) (Albion)		
Chromium (ChromeMate®)(from Chromium Polynicotinate)	50 mcg	42%
Molybdenum	25 mcg	33%
(from Molybdenum Glycinate Chelate) (TRAACS®) (Albion)		
Sodium	85 mg	4%
Potassium	150 mg	4%
MCT Oil (Medium Chain Triglycerides)	3.0 g (3,000 mg)	†
Glycine	1.6 g (1,600 mg)	†
PectaSol® Modified Citrus Pectin	1.0 g (1,000 mg)	†
Organic Golden Flax Meal	1.0 g (1,000 mg)	†
L-Lysine (as L-Lysine HCl)	250 mg	†
Stevia Extract (<i>Stevia rebaudiana</i>) (Leaf)	165 mg	†
Taurine	100 mg	†
MSM (Methylsulphonylmethane)	100 mg	†
NAC (N-Acetyl Cysteine)	50 mg	†
Milk Thistle Extract (<i>Silybum marianum</i>)	50 mg	†
(Fruit and Seeds) (Standardized to min.80% Silymarin Flavonoids)		
TMG (Trimethylglycine) (Betaine Anhydrous)	50 mg	†
Green Tea Extract	50 mg	†
(<i>Camellia sinensis</i>) (Leaf) (Standardized Extract) [min. 98% Total Polyphenols, 80% Total Catechins and 50% EGCG (Epigallocatechin Gallate) (25 mg)]		
Broccoli Concentrate	50 mg	†
(Contains min. 2% Total Glucosinolates)		
Choline Bitartrate	50 mg	†
Alpha-Lipoic Acid	30 mg	†
(from ProtoSorb™C)		
Coenzyme Q10 (CoQ10)	25 mg	†
L-Glutathione	25 mg	†
Inositol	25 mg	†
Boron (from Boron Amino Acid Chelate)	330 mcg	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Rice Protein Concentrate (from Non-GMO Brown Rice), Organic Brown Rice Syrup, Natural Flavors, Natural Beet Powder (for color) and Xanthan Gum. ProtoClear™ is free of yeast, wheat, gluten, soy protein, milk, egg, nuts, shellfish, preservatives, and artificial colors, flavors or sweeteners.

**Co-enzyme Forms

ChromeMate® is a registered trademark of InterHealth Nutraceuticals Inc. (US Patent Nos. 4,923,855, 4,954,492 and 5,194,615).

TRAACS® (The Real Amino Acid Chelate System) is a registered trademark of Albion Laboratories, Inc. PectaSol® is a registered trademark of EcoNugenics®, Inc. PectaSol® is protected under US Patent No. 6,462,029, 6,274,566 and 7,026,302.

Vitamin D-3

With more patients avoiding exposure to the sun's UV rays, many are being deprived of the vitamin D they need for optimal health. In addition to its structural support benefits, researchers have examined its effect on dental, colon and breast health, cell abnormalities, nervous system function, mental health, and immune system function.* Accordingly, supplementation has proven to be a safe and effective way to ensure that the body is receiving an adequate supply. Protocol for Life Balance™ Vitamin D3 Softgels offer among the highest potencies available. Vitamin D3 (as Cholecalciferol) is easy absorbed and utilized by the body, and has extremely low toxicity. Each easy-to-swallow softgel contains 2,000 IU of natural Vitamin D3. Ongoing clinical studies continue to suggest that supplementing Vitamin D3 in higher potencies may offer ever greater health benefits.*



*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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September - October 2008

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