



## Clean & Lean-14®

NUTRACEUTICALS  
Transformation Through Detoxification\*

### Clinical Applications

- Supports Healthy Immune Function\*
- Supports the Body's Defenses Against Seasonal Immune Challenges\*
- Supports Hematopoiesis Following Radiation and Other Bone Marrow Insults\*

*ImmunoFy's active ingredient is beta 1,3/1,6 glucan, a unique complex carbohydrate purified from Saccharomyces cerevisiae (baker's yeast). It is natural, not genetically modified (non-GMO), hypoallergenic, patented, and generally recognized as safe (GRAS). Taken orally, ImmunoFy, without over-stimulating, primes and mobilizes cells in the body's first line of defense to enhance protection against harmful effects of lifestyle and physical stressors.\**

All Clean&Lean-14 Formulas Meet or Exceed cGMP Quality Standards

Manufactured for: Clean&Lean-14®  
P.O. Box 175H  
Scarsdale, NY 10583  
Phone: 914-740-3788  
Email: Clean14detox@gmail.com  
Website: CleanLean14.com

## Discussion

Beta-glucan has been recognized for its support of immune system activity for centuries<sup>[1]</sup>; and yeast-derived beta-glucan has become the subject of over 800 scientific studies to date. ImmunoFy contains concentrated 1,3/1,6 beta-glucan from the yeast *Saccharomyces cerevisiae*, a source known to support immune function.<sup>[2-4]</sup> Beta-glucan is produced by fungi, grains, seaweed, and yeast, but not by mammalian cells.<sup>[3-5]</sup> While each source of beta-glucan has its own unique structure of glucose linkages, purified yeast-derived beta-glucan from *S cerevisiae* is considered the most effective source.<sup>[6,7]</sup> Purity of the product is vital, since protein contaminants can cause untoward immune reactions. Clean&Lean-14's ImmunoFy 500 is refined to remove most impurities, including proteins and fats that can interfere with uptake and effectiveness. Mannan, a potential trigger of allergic reactions or bowel exacerbation, has been removed. ImmunoFy 250 provides 250 mg beta-glucan per capsule, while ImmunoFy 500 provides 500 mg beta-glucan per capsule.\*

Ongoing research has unveiled a detailed mechanism of action, including activation of macrophages, neutrophils, and T-cell-mediated immunity.<sup>[3,8,9]</sup> Orally administered yeast beta-glucan is processed by macrophages—the first line of defense in cellular immunity<sup>[8]</sup>—with subsequent increases in phagocytosis, selective cytokine release, and oxidative degranulation.<sup>[10]</sup> Macrophages degrade beta-glucan into small fragments that are then bound to neutrophils (granulocytes), the most abundant immune cells in the body. Neutrophils then become primed and are better able to provide support against microbial challenges.<sup>[4]</sup> Through a process called chemotaxis, these primed neutrophils migrate to target sites with enhanced immune actions.<sup>[3,11]</sup> Prophylactic administration of beta-glucan was found to positively affect levels of the antioxidant enzymes catalase and superoxide dismutase, moderate tissue-damaging cytokines, and assist in ameliorating microbial imbalance.\*<sup>[12]</sup>

Research demonstrates a sustained release of soluble fragments over a multi-day period, providing a unique mechanism of action for the beta-glucan form found in ImmunoFy 500. Studies also indicate that the entrance of these soluble fragments into the bone marrow may affect white-blood-cell recovery, further enhancing its health effects.<sup>[13]</sup> Individuals at increased risk for immune challenges, those in need of immune support, or those undergoing surgery have been found to benefit from ImmunoFy 500.<sup>[2,6,8,12,14]</sup> A 12-week, randomized, phase II, double-blind, placebo controlled, parallel-group trial of 1,3/1,6 beta-glucan from *S cerevisiae* was conducted. Long-term use of beta-glucan was well tolerated and resulted in a reduction in acute immune challenge discomforts.\*<sup>[2]</sup>

\*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.



## ImmunoFy 500 60c

### Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 60

	Amount Per Serving	%Daily Value
Whole Glucan Particle (providing beta-glucan naturally derived from <i>Saccharomyces cerevisiae</i> )	500 mg	**

\*\* Daily Value not established.

**Other Ingredients:** Dicalcium phosphate anhydrous, HPMC (capsule), stearic acid, magnesium stearate, silica, and medium-chain triglyceride oil.

#### MAY BE COVERED BY ONE OR MORE OF THE FOLLOWING PATENTS AND APPLICATIONS:

US 7,981,447; US 7,022,685; US 7,566,704; US 6,369,216; US 5,702,719 and patents pending.

### Does Not Contain

Wheat, gluten, corn, yeast protein, soy, animal or dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

## ImmunoFy 250 30c

### Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 30

	Amount Per Serving	%Daily Value
Whole Glucan Particle (providing beta-glucan naturally derived from <i>Saccharomyces cerevisiae</i> )	250 mg	**

\*\* Daily Value not established.

**Other Ingredients:** Dicalcium phosphate anhydrous, HPMC (capsule), stearic acid, magnesium stearate, silica, and medium-chain triglyceride oil.

**MAY BE COVERED BY ONE OR MORE OF THE FOLLOWING PATENTS AND APPLICATIONS:** US 7,981,447; US 7,022,685; US 7,566,704; US 6,369,216; US 5,702,719 and patents pending.

### References

- Tian J, Ma J, Wang S, et al. Increased expression of mGITRL on D2SC/1 cells by particulate  $\beta$ -glucan impairs the suppressive effect of CD4(+)CD25(+) regulatory T cells and enhances the effector T cell proliferation. *Cell Immunol.* 2011 May 10;270(2):183-7. [PMID: 21636079]
- Feldman S, Schwartz HI, Kalman DS, et al. Randomized phase II clinical trials of Wellmune WGP<sup>®</sup> for immune support during cold and flu season. *J Appl Res.* 2009 March-June;9(1&2):30-42. <http://jrnlappliedresearch.com/articles/Vol9Iss1/FeldmanVol9No1.pdf>. Accessed September 9, 2011.
- Driscoll M, Hansen R, Ding C, et al. Therapeutic potential of various beta-glucan sources in conjunction with anti-tumor monoclonal antibody in cancer therapy. *Cancer Biol Ther.* 2009 Feb;8(3):218-25. [PMID: 19106638]
- Liang, J., D. et al. Enhanced clearance of a multiple antibiotic-resistant *Staphylococcus aureus* in rats treated with PGG-glucan is associated with increased leukocyte counts and increased neutrophil oxidative burst activity. *Int J Immunopharmacol.* 1998 Nov;20(11):595-614. [PMID: 9848393]
- Vetvicka V. Glucan-immunostimulant, adjuvant, potential drug. *World J Clin Oncol.* 2011 Feb 10;2(2):115-9. [PMID: 21603320]
- Vetvicka V, Terayama K, Mandeville R, et al. Pilot study: orally-administered yeast  $\beta$ 1,3-glucan prophylactically protects against anthrax infection and cancer in mice. *JANA.* 2002;5(2):5-9. Reprint. <http://www.ana-jana.org/Journal/journals/JANAVol52.pdf>. Accessed August 21.
- Natural Standard Database <http://naturalstandard.com>. Accessed July 23, 2011.
- Yan J, Allendorf DJ, Brandley B. Yeast whole glucan particle (WGP) beta-glucan in conjunction with antitumor monoclonal antibodies to treat cancer. *Expert Opin. Biol Ther.* 2005 May;5(5):691-702. [PMID: 15934844]
- Qi C, Cai Y, Gunn L, et al. Differential pathways regulating innate and adaptive antitumor immune responses by particulate and soluble yeast-derived  $\beta$ -glucans. *Blood.* 2011 Jun 23;117(25):6825-36. [PMID: 21531981]
- Pelizon AC, Kaneno R, Soares AM, et al. Immunomodulatory activities associated with beta-glucan derived from *Saccharomyces cerevisiae*. *Physiol Res.* 2005;54(5):557-64. [PMID: 16238470]
- Tsikitis V, Albina J, Reichner J. Beta-glucan affects leukocyte navigation in a complex chemotactic ingredient. *Surgery.* 2004 Aug;136(2):384-9. [PMID: 15300205]
- Senoglu N, Yuzbasioglu MF, Aral M, et al. Protective effects of N-acetylcysteine and beta-glucan pretreatment on oxidative stress in cecal ligation and puncture model of sepsis. *J Invest Surg.* 2008 Sep-Oct;21(5):237-43. [PMID: 19160131]
- Turnbull, JL, Patchen ML, Scadden DT. The polysaccharide, PGGglucan, enhances human myelopoiesis by direct action independent of and additive to early-acting cytokines. *Acta Haematol.* 1999;102(2):66-71. [PMID: 10529508]
- Kournikakis B, Mandeville R, Brousseau P, et al. Anthrax-protective effects of yeast beta 1,3 glucans. *Med Gen Med.* 2003 Mar 21;5(1):1. [PMID:12827062]

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## ImmunoFy 500 20c

### Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 20

	Amount Per Serving	%Daily Value
Whole Glucan Particle (providing beta-glucan naturally derived from <i>Saccharomyces cerevisiae</i> )	500 mg	**

\*\* Daily Value not established.

**Other Ingredients:** Dicalcium phosphate anhydrous, HPMC (capsule), stearic acid, magnesium stearate, silica, and medium-chain triglyceride oil.

#### MAY BE COVERED BY ONE OR MORE OF THE FOLLOWING PATENTS AND APPLICATIONS:

US 7,981,447; US 7,022,685; US 7,566,704; US 6,369,216; US 5,702,719 and patents pending.

### Directions

For ongoing immune support: Take one capsule daily, first thing in the morning or last thing at night (before or well after a meal), with a full 8 oz glass of water. For fast-acting immune support: Take up to two capsules per day, as above; or use as directed by your healthcare practitioner.\*

Consult your healthcare practitioner prior to use. Individuals taking medication should discuss potential interactions with their healthcare practitioner. Do not use if tamper seal is damaged.

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For ongoing immune support: Take one capsule daily, first thing in the morning or last thing at night (before or well after a meal), with a full 8 oz glass of water. For fast-acting immune support: Take up to two capsules per day, as above; or use as directed by your healthcare practitioner.\*

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### Does Not Contain

Wheat, gluten, corn, yeast protein, soy, animal or dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.