



Clean & Lean-14[®]
NUTRACEUTICALS
Transformation Through Detoxification*

NOTICE: This formula now contains an ingredient derived from milk.

Clinical Applications

- Supports Immune Function by Providing Immunoglobulins and Other Immune Factors*
- Supports the Body's Normal Gut Repair Pathways*
- Helps Maintain a Healthy Microbial and Cytokine Balance in the Gut*
- Promotes Overall Health and Well-Being*

*Immuno-IgG is an immunoglobulin concentrate derived from colostrum whey peptides. It delivers natural immunoglobulins (standardized to a minimum of 40% IgG), bioactive proteins, and growth factors. These components support immune function, healthy cytokine activity, gut barrier function, and gastrointestinal health and tissue repair. Advanced coagulation and filtration techniques make Immuno-IgG a unique, GRAS formula that is superior in its bioactive composition and its purity.**

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

Discussion

Beyond Colostrum: Immunoglobulin Concentrate from Colostrum Whey Peptides

Immuno-IgG is the result of advanced coagulation and filtration technologies that separate bioactive substances and then concentrate them. These precise systems produce a potent, pure, and generally recognized as safe (GRAS) immunoglobulin concentrate from colostrum whey peptides. Immuno-IgG provides immunoglobulins, including a minimum of 40% IgG; bioactive and growth factors; oligosaccharides; and gangliosides. Each of these components provides the user with different and complementary health benefits (see Chart).^{*[1]}

Immunoglobulins

Oral consumption of immunoglobulins derived from colostrum is a means of supporting passive immunity.^[2-5] Immunoglobulins flag antigens for the immune system. In doing so, immunoglobulins become key participants in protecting the body and eliminating unwanted molecules. Immuno-IgG delivers immunoglobulins and is particularly high (minimum of 40%) in IgG. Among immunoglobulins, IgG is said to be the most versatile, carrying out all of the functions of immunoglobulin molecules.*

Bioactive and Growth Factors

Sialic acid is an essential component of mucins, glycoproteins, oligosaccharides, and gangliosides and is therefore important to the function of cell membranes and membrane receptors. It is also important for normal brain development. Sialic acid-containing oligosaccharides in bovine colostrum can prevent certain antigens from binding to host tissues. Lactoferrin is an immune-supporting, iron-binding glycoprotein naturally found in bovine colostrum. It plays an important role in immune regulation and in the body's defense mechanisms.^[6] Studies suggest that growth factors from bovine colostrum, including IGF-1 (insulin-like growth factor) and TGF (transforming growth factor), stimulate cell growth in the gut to strengthen the gut lining, help build lean muscle mass, and slow protein catabolism.^[1] Furthermore, improvements observed in exercise performance by athletes taking colostrum have been attributed to growth factors.*

Proline-Rich Peptides

Proline-rich peptides (PRPs), which were first isolated from ovine colostrum and later from bovine colostrum, are intercellular signaling molecules. They act as regulatory substances that have the unique ability to modulate and stabilize various biologic processes in the body, such as cytokine and immune processes.

^[1] The in vitro and in vivo effects of PRPs on immunoregulation, including their effects on the maturation and differentiation of thymocytes and humoral and cellular immune responses, have been demonstrated. Also of great interest are the many studies suggesting their beneficial effects on age-associated changes in neurological health.^[7] For instance, in vivo work revealed that PRPs alleviate beta-amyloid cytotoxicity in hippocampal neuronal cells; in humans, PRPs provided an early beneficial effect on cognitive symptoms and daily functioning at a dose as low as 100 mcg/d every other day.^[8,9] Five grams of powder or eight capsules of Immuno-IgG provides 1% to 2% (50 to 100 mg) PRPs.*

Oligosaccharides

Bovine milk oligosaccharides, which are a component of lactose, are modulators of gut microbiota. They provide protection by acting as decoys to attract antigens and inhibit them from binding to epithelial surfaces of the intestine.^[10] Evidence also suggests that oligosaccharides act as growth promoters for a selected class of beneficial bacteria^[11] and contribute to the development and maturation of the intestinal immune response.^[12] Approximately 66 acidic and neutral oligosaccharides, including sialyloligosaccharides, which are known for their high biological activity in humans, have been detected in IgG concentrate from colostrum whey peptides.^{*[13]}

Gangliosides

Gangliosides are vital to the structure and function of cell membranes. They support neural development, and they have roles in supporting gut integrity, influencing immune cell signaling, modulating cytokine activity and production, and affecting the adherence and toxin production of antigens.^[14-17] Research has demonstrated that providing gangliosides in the diet increases ganglioside content in the intestinal mucosa. Studies have indicated that low levels of gangliosides in the intestinal mucosa are associated with increased levels of cytokines, susceptibility to antigens, and poor gut integrity.^[14] The ganglioside composition of bovine milk is predominately GM3 and GD3.^{*[15]}

Immuno-IgG Studies

Building on the extensive literature pointing to the health benefits associated with bovine-derived colostrum and colostrum whey, scientists performed in vitro, in vivo, and human clinical studies using Immuno-IgG to demonstrate its bioactivity and effectiveness. In vitro, Immuno-IgG was shown to support the body's normal repair pathways by stimulating the migration and production of gut epithelial cells.^[16] In an in vivo model of gut integrity challenge, rats administered

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***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.**

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

IMMUNO-IgG



Chart: Bioactive Compounds in Immuno-IgG

Active	Key Function(s)
Immunoglobulins	Immune support*
Growth Factors	Lean mass support, cell and tissue repair and rejuvenation*
Sialic Acid	Immune modulation, brain health, prebiotic*
Lactoferrin	Immune support*
Proline-Rich Peptides (PRPs)	Immune modulation, brain and thymus support*
Oligosaccharides	Microbiota modulation*
Gangliosides	Immune cell signaling*

Immuno-IgG Capsules

Supplement Facts

Serving Size: 2 Capsules
Servings Per Container: 60

	Amount Per Serving	%DV†
Calories	5	
Protein	1 g	
Immuno-IgG (bovine-derived immunoglobulin concentrate)	1 g	**
Immunoglobulin G (IgG)	400 mg	**

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

Other Ingredients: Capsule (hypromellose and water), silica, and sunflower lecithin.

Contains: Milk

Directions

Take two capsules twice daily, or 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.

References

- Godhia M, et al. *Curr Res Nutr Food Sci*. 2013;1(1):37-47. <http://dx.doi.org/10.12944/CRNFSJ.1.1.04>
- Hurley D. [Dissertation]. Brookings, SD: South Dakota State University; 1994.
- Hurley WL, et al. *Nutrients*. 2011 Apr;3(4):442-74. [PMID: 22254105]
- Rump JA, et al. *Clin Investig*. 1992 Jul;70(7):588-94. [PMID: 1392428]
- Schaller JP, et al. *J Infect Dis*. 1992 Apr;165(4):623-30. [PMID: 1313067]
- Berlutti F, et al. *Molecules*. 2011 Aug 16;16(8):6992-7018. [PMID: 21847071]
- Janusz M, et al. *Cell Mol Biol (Noisy-le-grand)*. 2013 Nov 3;59(1):4-11. [PMID: 24200016]
- Froud KE, et al. *J Alzheimers Dis*. 2010;20(2):423-26. [PMID: 20164569]
- Bilikiewicz A, et al. *J Alzheimers Dis*. 2004 Feb;6(1):17-26. [PMID: 15004324]
- Lane JA, et al. *Int J Food Microbiol*. 2012 Jul 2;157(2):182-8. [PMID: 22647676]
- Aldredge DL, et al. *Glycobiology*. 2013 Jun;23(6):664-76. [PMID: 23436288]
- Lane JA, et al. *Br J Nutr*. 2013 Dec;110(12):2127-37. [PMID: 23710626]
- Barile D. Milk oligosaccharides. Confidential Report. Brookings, SD: Sterling Technology; 2011. [on file]
- Miklavcic JJ, et al. *J Nutr Metab*. 2012;2012:280286. [PMID: 22506104]
- Lee H, et al. *J Agric Food Chem*. 2013 Oct 9;61(40):9689-96. [PMID: 24024650]
- Sánchez-Juanes F, et al. *Biol Chem*. 2009 Jan;390(1):31-40. [PMID: 18937626]
- Park EJ, et al. *J Pediatr Gastroenterol Nutr*. 2010 Mar;50(3):321-28. [PMID: 20118807]
- Playford R. [Unpublished colostral studies]. London, UK: Hammersmith Hospital; 2007.
- Satyarayaj E, et al. *Br J Nutr*. 2013 Dec;110(12):2216-21. [PMID: 23773360]
- Jensen G, et al. Interim Report 9B. Brookings, SD: Sterling Technology. September 2010. [on file]
- Playford RJ, et al. *Clin Sci (Lond)*. 2001 Jun;100(6):627-33. [PMID: 11352778]

Does Not Contain

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

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

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Immuno-IgG showed significant improvements in both microscopic and macroscopic mucosal health. [18] Supplemented dogs showed a significantly higher vaccine response and higher levels of fecal IgA when compared with the control group. These results were indicative of an enhanced immune status. Researchers also observed increases in gut microbiota diversity and stability in the supplemented dogs. [19] In humans (n = 12), 1000 mg/d of Immuno-IgG increased salivary IgA by 30%, improved quality of life scores, significantly increased the ability to perform activities of daily living, improved hyperimmune responses, and reduced minor health complaints by 47%. [20]

In a randomized, crossover trial (n = 7), a five-day challenge to gut integrity caused a three-fold rise from baseline in gut permeability as measured by lactulose/rhamnose ratios. Co-administration of a 15% IgG colostrum formula inhibited this increase. [21] When the same researchers compared the RPF[†] (repair and protection factor) of the 15% IgG colostrum formula to Immuno-IgG, which is a 40% IgG formula, the Immuno-IgG score was two times higher. This suggests that Immuno-IgG would offer even greater results in supporting gut integrity than did the 15% IgG colostrum formula.*

†RPF is a novel (patent pending) analytical method that evaluates a product's bioactive properties to determine its effectiveness in repairing damaged cells and protecting healthy cells.

Immuno-IgG Powder

Supplement Facts

Serving Size: 1 Tablespoon (about 5 g)
Servings Per Container: About 25

	Amount Per Serving	%DV
Calories	20	
Protein	4 g	
Calcium (from Immuno-IgG)	40 mg	4%
Immuno-IgG (bovine-derived immunoglobulin concentrate)	5 g	**
Immunoglobulin G (IgG)	2 g	**

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

Other Ingredients: Sunflower lecithin.
Contains: Milk.

Directions

Mix one tablespoon (about 5 g) into 2-4 oz of water and consume daily, or take 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.