



(dietary supplement)

# Highlights Of Prescribing Information

HyperIg PL100<sup>®</sup> Dietary Supplement (Hyperimmune Egg (HIE) Powder, Polyvalent Hyperimmune Egg)

#### DESCRIPTION

Hyperlg PL100® is whole egg protein from hens stimulated multiple times with >26 different inactivated bacteria of human-interest including *Salmonella*, *Staphylococcus*, *Streptococcus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas*, *Proteus*, *Propionibacterium acnes*, *and Hemophilus influenzae*.

*In vitro,* in vivo and human trials suggest that the naturally occurring immune components in hyperimmune egg (HIE) are preferentially selected by the body to help it return to, and/or achieve, inflammatory immune homeostasis.

An independent panel of experts qualified by their scientific training and experience to represent the scientific community at large, conferred self-affirmed GRAS ("generally recognized as safe") status to hyperimmune egg. The results of the Expert Panel were submitted to the FDA, which then issued a Food Master File. This all-natural ingredient has been on the market for more than a three decades.

Over 100 U.S. and international patents and patent applications protected the technology.

Like all eggs, these eggs have as their dominant, unique immunoglobulin class IgY. Even after exposure to gastrointestinal enzymes, the Fab(2) units of orallyadministered immunoglobulins appear to survive intestinal enzymatic activity and are able to neutralize microorganisms against which they were produced.

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Although both table eggs and "hyperimmune" eggs contain equivalent levels of IgY and identical immunoregulatory factors, eggs from "hyperimmunized" chickens contain many-fold greater concentrations of their naturally occurring bioactive factors as compared to typical eggs (Unpublished).

Along with the production of specific immunoglobulins, stimulation of the hens results in increases in naturally occurring bioactive molecules with potent pro-, and anti-inflammatory, properties.

The immune system is a tightly regulated network that maintains a balance of immune homeostasis under normal physiological conditions. This balance is disrupted as the body defends itself against pathogens, mutating cells, and during tissue repair. The biological factors in HyperIg PL100 help the body maintain immune homeostasis by partnering to help it appropriately modulate immunological responses, especially those of an autoimmune or inflammatory nature. Thus, hyperimmune egg *balances*, but does not "boost" immunological responses the body deems it necessary.

#### **INDICATIONS AND USAGE**

HyperIg PL100 is defined under the Dietary Supplements Health and Education Act (DSHEA) as a dietary supplement and as such is not intended to diagnose, prevent, treat, or cure disease. Statements as to function have not been evaluated by the Food and Drug Administration.

The immunoglobulins and other immune factors in HyperIg PL100 are an allnatural source for the body to select those elements it needs to help the body maintain intestinal tract health, flexible and active joints, support health cholesterol levels already in normal range, cardiovascular function and healthy circulatory systems, affect energy levels and the feeling of well-being.

# **Clinical Pharmacology**

Upon oral administration of hyperimmune egg, a wide range of immune components, both of a specific and non-specific nature, are passively transferred. Although the immunoglobulins are confined to the lumen, other smaller, bioactive immune components appear to have systemic effects. This may occur via: a) indirectly by activating cells in the GALT (gut-associated lymphoid tissue) which then migrate out of the intestine with the appropriate message, or b) by directly crossing the GI barrier and circulating to the sites

where they modulate inflammatory and other immune responses (US Patent # 7083809).

# **Optimizing Immune Homeostasis**

*In vitro*, factors in hyperimmune egg appear to control the production of cytokines such as tumor necrosis factor (TNF-alpha). Pro-inflammatory cytokines, such as TNF-alpha, IL-1b, and IL-2 from stimulated human monocyte cultures are completely inhibited in the presence of HIE. PGE2 biosynthesis by mouse monocytes in vitro is also inhibited upon the addition of hyperimmune egg fractions. (US Patent #7083809B2)

In an in vivo model of a carrageenan-induced skin disorder, administration of HIE resulted in a 50% decrease in the size of the resulting injection sites as compared with controls (Unpublished).

Under certain circumstances, in vitro assays demonstrate that hyperimmune egg stimulate the growth of CD4+ cells.

# **Joint Comfort**

In vivo studies report modulation of the incidence and severity of laboratoryinduced joint destruction, including a reduction in the level of anti-collagen autoantibodies and decreased migration of inflammatory immune cells into joint tissues.

An open-label clinical trial conducted at The Hospital for Special Surgery in New York, NYC, the daily consumption of 4.5g of HIE resulted in statistically significant decreases in the daily aches and discomfort associated with daily life.

[Combining polyvalent hyperimmune egg with certain forms of glucosamine-HCI may result in a synergistic effect when addressing joint issues. *In vivo*, the combination of hyperimmune egg and certain glucosamines, results in lower serum fibrinogen levels, and decreased swelling of adjacent soft tissues. Additionally, decreases in bone overgrowth and joint cartilage erosion were reported.]

# **Circulatory and Cardiovascular Health**

Hyperimmune egg has been demonstrated to help the body control several key indices of cardiovascular health. Rabbits on a high cholesterol diet and

hyperimmune egg were able to maintain normal ranges of total serum cholesterol levels, while inhibiting plaque formation.

In a 26-week randomized, placebo-controlled study conducted by the United States Military, test subjects consuming hyperimmune egg maintained healthy cholesterol levels and stable total cholesterol to HDL ratios. Additionally, these subjects were able to more easily regulate their serum lipoprotein levels.

In an pilot clinical trial, individuals on 9 grams/day of HIE showed statistically significant reductions (within 95% confidence levels) of hs-CRP at 6 weeks (Unpublished).

# **Gastrointestinal Health**

Hyperimmune egg contains bioactive immunoregulatory factors and immunoglobulins, especially IgY. These factors influence the cells of the GALT (gut-associated lymphoid tissue) both directly and indirectly.

Pre-administration of hyperimmune egg 1-2 days prior to challenge with castor oil in vivo, significantly inhibited diarrheal episodes in a dose-related manner. Daily consumption of HIE helped the body naturally regulate intestinal transit.

In vivo, long-term ingestion of hyperimmunized egg is cytoprotective against induced intestinal ulceration and alleviates certain destructive effects that accompany such challenge.

Hyperimmune egg significantly improves markers of gut health associated with intestinal wall health. It balances beneficial flora and reduces gut wall permeability. Individuals report decreases in gas and bloating and fewer over histaminergic complaints, significantly increasing QoL parameters.

Hyperimmune egg increases the occurrence of *Lactobacillus, Bactoroides fragilis, and Bifidobacterium* beneficial microbiome species (Unpublished).

# **Enhanced Athletic Performance, Stamina, Recovery**

In a randomized, double-blind, placebo-controlled university trial, subjects utilizing 13.5g daily of hyperimmune egg experienced greater athletic performance as measured by endurance, recovery and strength. HIE appears to help the body lower intrinsic heart rates, and stimulate muscle growth and repair resulting in better performance. They reported higher levels of both anaerobic and aerobic performance, with less effort when using hyperimmune egg. Professional athletes report similar findings.

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Published university trials demonstrate that consumption of hyperimmune egg results in more muscular power with less effort, increased muscle repair and upper body muscular strength, greater endurance, shorter recovery times after intense workouts, significantly less muscle soreness 24 h after intense activity and the ability to achieve high levels of both high levels of anaerobic and aerobic energy.

Oral consumption of hyperimmune egg appears to mediate the extent of inflammatory responses due to muscle damage following induced delayed onset muscular soreness (DOMS). It decreases submaximal heart rate while not affecting performance and speeds muscle repair.

Reports from athletes detail that they are able to get and stay "in the zone/flow" faster and longer, have greater tolerance of extreme temperatures, increased speed, fewer injuries experienced and faster healing when injured, greater levels of confidence, great stamina even after back-to-back competitions, and the ability to stay positive and handle stress, anxiety and pressure more easily.

### **Maintain Healthy Weight in Populations at Risk**

Hyperimmune egg helps maintain or increase lean muscle mass in individuals experiencing involuntary, weight changes (US Patent #6803035).

# **Quality of Life (Qol) Parameters**

HIV/AIDS subjects consuming 6.0g of HIE showed marked improvement in many quality of life issues including energy, weight, appetite, sleep quality, gastrointestinal and pulmonary function as well as changes in their CD4 counts (Unpublished).

In a human trial in India with HIV/AIDS individuals, 88.2% [n=17] either maintained their weight or gained weight (lean muscle mass) after 60days on 6.0g of hyperimmune egg (Unpublished). Weight gains were from 0.5kg to 6 Kg and in some cases the gains amounted to a 10% increase over their initial weight.

Quality of life indexes showed marked differences both in the physical and emotional status of HIV/AIDS subjects. Attacks of abdominal pain, respiratory stress, diarrhea, muscle discomfort, and headaches, were reduced, whereas weight, appetite, strength, and feelings of well being increased. (Unpublished).

In quality of life trial in Uganda, 62-outpatient, HIV positive individuals receiving 4.5g of HIE experienced changes in the following parameters: headache,

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insomnia, appetite, nausea or vomiting, diarrhea, abdominal pain, muscle and joint ache, muscle wasting, fatigue, cough, chest pain, and skin rash (Unpublished).

In a separate study in Kenya, within 7d of being on 4.5 g of hyperimmune egg, >75% of 139 HIV/AIDS subjects reported changes in their gastrointestinal, cardiac, and central nervous system comfort. By d21, daily discomfort parameters had decreased by 60% and by d56, 90% reductions in symptoms were reported. The longer the patients survived, the more they reported feeling "relatively well". Hospitalization stays were reduced by 4d (Unpublished).

### SERVINGS AND ADMINISTRATION

Recommended servings are 4.5g-9g/daily for maintenance, more as desired. Most of the smaller bioactive immune components in HyperIg PL-100 are heatstable, but boiling temperatures may denature the immunoglobulins. Individuals can consume HyperIg PL100 with water or it can be added to most foods or beverages, such as puddings, yogurts, salads, juices, etc.

Each serving of HyperIg PL100 contains 4.5 grams of pure, hyperimmune egg protein. It is suggested that HyperIg PL100 be gradually added to one's diet:1 g/daily (1/4 of a serving) for 3-4d, 2g/daily (1/2 of a serving) for 3-4d, 4.5g/daily (whole serving) for 3-4d, etc.

**Note:** HyperIg PL100 may be used concomitantly with prescription medications.

#### CONTRAINDICATIONS

HyperIg PL100 is contraindicated in individuals with a history of extreme hypersensitivity or life-threatening allergy to orally administered egg.

#### WARNINGS AND PRECAUTIONS

For especially sensitive individuals, starting with 0.5g (1/8 of a scoop) of HyperIg PL100/day for 3-4 days successively is prudent, then doubling the amount every few days or so. Also, it is advisable that diabetics monitor their blood glucose levels more frequently while introducing this product into their diets, since some individuals appear to reach glucose homeostasis rapidly.

#### **ADVERSE REACTIONS**

Adverse reactions rarely occur, especially if individuals introduce this ingredient into their diets gradually. In two randomized double-blind, placebo-controlled trials (one with the US Military, the other at a University) the hyperimmune egg was well-tolerated. There was 82% compliance in a US Military study and 100% compliance In the University study. In the latter study, 2/12 subjects from the placebo group and 3/12 subjects from the PL-100 group reported GI disturbances. The placebo group reported average GI disturbance severity as a "seven", compared to the "two" score of the active ingredient group.

#### **HOW SUPPLIED**

As a powder: HyperIg PL100. (140g/31 servings/canister)

#### Storage

Best kept dry with the lid tightly shut. A cool location is suggested.

References and unpublished data provided upon request.

\* 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.

#### **PRODUCT PHOTO**

NOTE: These photos can be used only for identification by shape, color, and imprint. They do not depict actual or relative size.

The product samples shown here have been supplied by the manufacturer and reproduced in full color by PDR as a quick-reference identification aid. While every effort has been made to assure accurate reproduction, please remember that any visual identification should be considered preliminary. In cases of poisoning or suspected over dosage, the drug's identity should be verified by chemical analysis.

All-natural HyperIg <sup>®</sup> goes beyond nutrition to maintain optimal immune function by regulating and supporting:		
Increased Energy Levels*	A Healthy Digestive System	
Healthy Cholesterol Levels*	Flexible & Healthy Joints*	
A Healthy Circulatory System*	Healthy Cardiovascular Function*	

**SUGGESTED USE:** As a dietary supplement, blend or shake one scoop in any cold liquid such as fruit juice or milk. Sprinkle on any cold food such as salad, ice cream, yogurt or cereal. Use at least one to two times daily or as often as desired. For best results take in conjunction with a balanced diet and increased physical activity. Keep in a cool, dry place.

**CAUTION:** As with all products that contain eggs, persons with severe egg allergies should consult a health professional before using this product.

\* 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.

Beyondigy LLC assumes no responsibility and/or liability for any oral or written claims made by its distributors, customers, employees or advocates.

MADE IN THE USA

Patents:

US:5,772,999;6,803,035;6,420,337 European:166905;0152270;3504221; 93916420.8 Japan:2548115;2698778;1276883 Canada:1275044;1276883 Auatralia:583808;690521 New Zealand:333695;211030;254326;329033 All Natural, Sugar & Lactose Free

# **Supplement Facts**

Serving Size: 1 Scoop (4.5g) Servings Per Container: 31

	Amount Per Serving	%Daily Value*	
Calories Calories from Fat Total Fat: Saturated Fat Cholesterol Sodium Protein	20 t 15 2 g 0.5 g 75.6 mg 20 mg 2 g	2%** 3%** 25% <1% 4%**	
Calcium (from egg powder)2%Iron (from egg powder)2%			
Whole Egg Powder 4.5 g * * *Daily Values are based on a 2,000 calories diet. * Daily value not established.			
Other Ingredients: None Contains:Egg			

