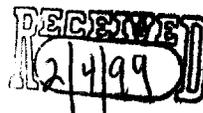


**PHARMATON**  
NATURAL HEALTH PRODUCTS

5 1 9 9 '99 FEB 19 P3:03

Robert P. Carraher  
EXECUTIVE DIRECTOR, MARKETING

February 2, 1999



VIA HAND DELIVERY

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-450)  
Washington, D.C. 20204

Re: GINSANA® SPORT Daily Energizing Dietary Supplement

To Whom It May Concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products (Pharmaton), Division of Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, wishes to notify the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label which bears statements of nutritional support. Pharmaton is the distributor of the product.

The dietary supplement for which the statements are made is GINSANA® SPORT SOFTGEL® Capsules, which consist of the ingredient standardized ginseng extract G115®, 200 mg per capsule.

The statements of nutritional support for this product read as follows:

- Daily energizing dietary supplement
- Helps maintain aerobic capacity during workouts
- Promotes efficient oxygen utilization
- Supports a healthy exercise regimen

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Office of Special Nutritionals  
February 2, 1999  
Page 2

GINSANA® SPORT helps maintain aerobic capacity during workouts by promoting efficient oxygen utilization to support a healthy lifestyle that includes proper diet and exercise.

When taken as directed GINSANA® SPORT is a natural way to enhance your physical endurance by improving your body's ability to utilize oxygen more efficiently.

GINSANA® SPORT will help you maintain your natural energy and overall feeling of healthy well-being.

A copy of the package for the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The information is printed in bold in a box.)

The Company certifies that it possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA, and that the information contained in this notice is complete and accurate.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Carraher', written in a cursive style.

Robert P. Carraher

Enclosure

Original plus two copies enclosed

# Ginsana Sport<sup>®</sup>

**CASH  
REBATE  
& Important  
information  
enclosed!**

## This Is GINSANA<sup>®</sup> SPORT.

These days, professional athletes aren't the only ones looking to enhance their physical performance. To stay on top in life, it takes a healthy, active lifestyle that includes an ample supply of work and play. Whether you work out every day or you're more of a "weekend warrior", GINSANA SPORT may help you get more out of your workouts... while you get more out of life.

GINSANA SPORT is a unique daily supplement for active people whose health and fitness are important to them. GINSANA SPORT helps maintain aerobic capacity during workouts by promoting oxygen utilization to help support a healthy lifestyle that includes proper diet and exercise.

GINSANA SPORT is proven safe. Unlike many workout supplements, it contains no caffeine and no artificial stimulants.

GINSANA SPORT contains the maximum proven daily dose of G115<sup>®</sup> ginseng, so one soft gelatin capsule each day as recommended is all you need to realize the benefits of GINSANA SPORT.

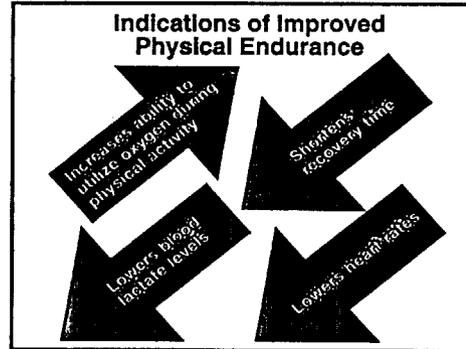
## Proven Safe and Effective

G115<sup>®</sup> is a natural standardized ginseng extract that contains the full range of active ginseng constituents called ginsenosides. This extract helps your body use oxygen more efficiently. Each GINSANA SPORT capsule is standardized, so it contains an equal and optimum amount of G115<sup>®</sup>, one of the most extensively researched ginseng extracts available. GINSANA SPORT will take time to reach its maximum effect. Take it regularly for four weeks and you'll see results. Make it part of a healthy regimen to play harder, go longer, and help you to be at your best.

## Helps Maintain Aerobic Capacity During Workouts

The G115<sup>®</sup> in GINSANA SPORT works with your body to improve endurance. Objective measurements of oxygen absorption, serum lactate levels, heart rate and blood chemistry changes are known to be important factors in measuring physical work performance and increased endurance. Clinical studies have shown that

G115<sup>®</sup> can lower serum lactate levels and heart rate. This means that GINSANA SPORT can help you perform work and physical activity more efficiently over longer periods of time.



## Promotes Efficient Oxygen Utilization

The human body needs an ample supply of oxygen to function properly. However, the body cannot store oxygen, making it imperative that the body is able to absorb and utilize oxygen as efficiently as possible. Oxygen absorption is regarded as important for peak performance and endurance. Clinical studies have shown that the unique G115<sup>®</sup> in GINSANA SPORT can improve oxygen absorption and utilization. Efficient use of oxygen can play a role in shortening recovery time after exercise.

## Long Term Safety

GINSANA SPORT contains the same natural extract found in GINSANA<sup>®</sup>, one of the most widely used natural supplements in the world. With over 25 years of international GINSANA experience, you can trust the long-term safety of GINSANA SPORT. Unlike many workout supplements, GINSANA SPORT contains no caffeine and no artificial stimulants.

## GINSANA<sup>®</sup> SPORT is standardized:

- Consistent level of dietary ingredients
- Predictable safety and efficacy



## Non-standardized supplements:

- Level of dietary ingredients varies
- Unknown safety and efficacy



## Frequently Asked Questions

### How does GINSANA SPORT work?

GINSANA SPORT's G115<sup>®</sup> ginseng extract is clinically shown to increase your body's oxygen uptake to help make the most of your natural, healthy energy. GINSANA SPORT energizes naturally without sugar, caffeine or artificial stimulants.

### What's the difference between GINSANA SPORT and other ginseng products?

GINSANA SPORT contains G115<sup>®</sup>, the same standardized ginseng extract made with the premium-quality Panax Ginseng, C.A. Meyer available in GINSANA<sup>®</sup>. This unique extract delivers a consistent level of ginsenosides (the active element of the root). Since GINSANA is a world leader supported by decades of clinical research, you can rely on the safety and efficacy of GINSANA SPORT.

### How long until I feel the results?

GINSANA SPORT is an herbal supplement, which means it works with your body. Because of this mode of action, it takes four weeks of continuous use to reach its maximum effect.

### Are there any side effects?

Many studies have been completed on the unique formulation of GINSANA SPORT and have shown only rare, mild adverse reactions: occasional headaches and gastrointestinal disturbances like gas, cramps, diarrhea and nausea. There have been reports of mild allergic skin reactions with the use of the extract in the product. Some consumers have reported that taking the product has caused drowsiness or sleeplessness.

### Can I take GINSANA SPORT with other supplements and vitamins or prescription drugs?

Yes. You can take GINSANA SPORT with any other vitamin, mineral or herbal supplement. You should also be able to take GINSANA SPORT with your prescription

medications as no serious or significant drug interactions have been reported, but, as with any supplement, it is recommended that you inform your doctor you are taking GINSANA SPORT if you are taking prescription drugs, are pregnant or lactating. You should take your prescription medications either an hour before or an hour after daily supplements.

### Will GINSANA SPORT raise my blood pressure?

GINSANA SPORT is not commonly known to raise blood pressure. It is recommended that you let your doctor know you are taking GINSANA SPORT and monitor your blood pressure daily. If you notice any changes, stop taking GINSANA and request a refund from Pharmaton Natural Health Products.

### What is an adaptogen?

GINSANA SPORT is an adaptogen, a substance that can help normalize body functions.

### Other Questions About GINSANA SPORT?

To receive more information about GINSANA SPORT, call toll free 1-800-203-2916 or visit us at our web site at <http://www.ginsana.com>.

## Directions for Use

**Recommended Adult Intake:** Adults over 12 years old should take one 200 mg soft gelatin capsule with water each morning. Research on doses above 200 mg per day does not substantiate any better effectiveness. Optimal results have been shown with 4 weeks of continuous use, taken as directed.

**Precautions:** As with vitamins and other supplements, please keep this product out of the reach of children. No serious or significant adverse reactions or drug interactions have been reported to date. However, as with any supplement, contact your doctor if you are taking a prescription medicine, are pregnant or lactating. There have been rare reports of mild allergic skin reactions with the use of the extract in this product. In case of accidental overdose, seek the advice of a professional immediately.

**The statements presented here have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Distributed by: **PHARMATON**  
NATURAL HEALTH PRODUCTS  
Ridgefield, CT 06877

GINSANA is a registered trademark of GPL, Ginsana Products Lugano, Switzerland. G115<sup>®</sup> is a registered trademark of Pharmaton, Ltd. © Copyright Boehringer Ingelheim Pharmaceuticals, Inc. 1999. All rights reserved. 882940

## To Receive Your GINSANA SPORT Cash Rebate

1. Complete the back of this certificate, and fill in your name and address.
2. Send this certificate along with the following:
  - Your cash register receipt (or a copy) with the purchase price of GINSANA SPORT circled.
  - The UPC symbol from the GINSANA SPORT carton.



Mail to: GINSANA SPORT Cash Rebate  
P.O. Box 6399  
West Caldwell, NJ 07007-6399

### Please complete the following:

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
Telephone: \_\_\_\_\_

Please allow 6-8 weeks for delivery of rebate check. Offer does not include Ginsana Chewy Squares. Void where prohibited, taxed or otherwise restricted. Limit one per household. This official certificate must accompany your request.

## Questions

1. What age category are you?  
 \_\_\_ 19 or younger \_\_\_ 20-25 \_\_\_ 26-35 \_\_\_ 36-49 \_\_\_ 50+
2. Sex: \_\_\_ Male \_\_\_ Female
3. What is your primary occupation?  
 \_\_\_ Student \_\_\_ Homemaker \_\_\_ Office (Clerical)  
 \_\_\_ Executive/Upper Management \_\_\_ Middle Management  
 \_\_\_ Health Care Professional/Nurse \_\_\_ Machine Operator  
 \_\_\_ Retired  
 Other: \_\_\_\_\_

4. About how often do you take ginseng?  
 \_\_\_ Daily \_\_\_ 2-6x per week \_\_\_ 1x per week  
 \_\_\_ Less than once per week
5. Is this the first time you've used GINSANA SPORT?  
 \_\_\_ Yes \_\_\_ No
6. How long have you been taking GINSANA SPORT?  
 \_\_\_ 1 to 5 months \_\_\_ 6 months to 1 year \_\_\_ 1 to 3 years  
 \_\_\_ 3+ years
7. Do you buy generic/store brand nutritional supplements?  
 \_\_\_ Always \_\_\_ Sometimes \_\_\_ Never



1-800-203-2916

**Ginsana<sup>®</sup>**  
**Sport**

**NEW** ORIGINAL STANDARDIZED G115<sup>®</sup> GINSENG EXTRACT  
**Ginsana<sup>®</sup>Sport**

**DAILY ENERGIZING DIETARY SUPPLEMENT**

**\$1.50**  
**Cash**  
**Rebate**  
**Inside**

- ▲ Helps Maintain Aerobic Capacity During Workouts
- ▲ Promotes Efficient Oxygen Utilization
- ▲ Supports a Healthy Exercise Regimen



*Safe, Natural Extract, No Caffeine or Stimulants*

Prove your better effectiveness.

GINSANA is a registered trademark of GPL, Ginsana Products, Lugano, Switzerland. G115 is a registered trademark of Pharmaton Ltd., Switzerland.

Distributed by: **PHARMATON**  
NATURAL HEALTH PRODUCTS Ridgefield, CT 06877

Product of Switzerland

*Safety sealed for your protection.  
Do not use if individual blister seals are broken.*

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All rights reserved.



**Ginsana<sup>®</sup>Sport**

ORIGINAL STANDARDIZED G115<sup>®</sup> GINSENG EXTRACT

8B2680

1-800-203-2916

**Ginsana<sup>®</sup>**  
**Sport**

**GINSANA SPORT** is a unique daily supplement for active people whose health and fitness are important to them. GINSANA SPORT helps maintain aerobic capacity during workouts by promoting efficient oxygen utilization to help support a healthy lifestyle that includes proper diet and exercise. GINSANA SPORT is proven safe. It contains no caffeine or artificial stimulants.

**Suggested Use:** When taken as directed, GINSANA SPORT is a natural way to enhance your physical endurance by improving your body's ability to utilize oxygen more efficiently. GINSANA SPORT will help you maintain your natural energy and an overall feeling of healthy well-being.

**Recommended Adult Intake:** Adults over 12 years old should take one 200 mg soft gelatin capsule with water each morning. Research on doses above 200 mg per day does not substantiate any better effectiveness. Optimal results have been shown with 4 weeks of continuous use, taken as directed.

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**SUPPLEMENT FACTS:**

Serving Size 1 capsule

Amount Per Capsule:

Standardized G115<sup>®</sup> Ginseng Extract  
(Panax Ginseng, C.A. Meyer) (root)200mg\*

\* Daily Value not established.

Other ingredients: Sunflower oil, gelatin, glycerin, beeswax, lecithin, tumeric, titanium dioxide, FD&C Green No.3.

**The statements presented on this package have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Contains no sugar, caffeine, or artificial stimulants.

**Store in a cool, dry place. Avoid excessive moisture and heat (above 86°F).**

Questions about GINSANA SPORT?  
Call toll-free 1-800-203-2916