



**2003 Physicians' Desk
Reference®**

The Authoritative Source of FDA-Approved Information on Prescription Drugs.

PDR® entry for

LIFEPAK®

OTC (Pharmanex)

Multivitamin/mineral/phytonutrient supplement

Multinutrient capsules in packets

Dietary Supplement

DESCRIPTION

LifePak is a comprehensive wellness program, delivering the optimum types and amounts of vitamins, minerals, trace elements, antioxidants, and phytonutrients for general health and well-being.* LifePak addresses all common nutrient deficiencies, such as vitamins A, E, B6, the bone nutrients calcium and magnesium, and the minerals iron and zinc; provides the key anti-aging nutrients such as alpha-lipoic acid, vitamins C, E, and B12, folic acid, flavonoids, and mixed carotenoids that promote cellular protection and regeneration; and supports cardiovascular health, bone metabolism, and normal immune function.* The amounts of vitamins and minerals included in LifePak were chosen not only to prevent vitamin and mineral deficiencies, but also to correct any pre-existing deficiencies with regular use.* LifePak is intended for the general adult population. Pharmanex also offers LifePak Women for premenopausal women, LifePak PreNatal for pregnant and lactating women, and LifePak Prime for men over age 40 and postmenopausal women.

SCIENTIFIC SUPPORT

LifePak's antioxidant and cardiovascular benefits are supported by two double-blind clinical studies. In a completely randomized crossover study, 25 subjects received LifePak, and 25 received placebo for 6 weeks. After a six-week washout period, the treatments were reversed. The results showed that LifePak significantly improved antioxidant status as evidenced by increased serum concentrations of ascorbic acid, (alpha)-carotene, (beta)-carotene, and vitamin E, with no changes in placebo treatment. Most important, LifePak significantly decreased LDL oxidizability, as the lag time was prolonged by 17 % and oxidation rate was reduced, with no changes in placebo treatment. Results also confirmed the assumption that a complex antioxidant nutrient combination can be efficacious in the presence of a full spectrum of non-antioxidant nutrients in a nutritionally complete vitamin/mineral/phytonutrient supplement.

A second LifePak clinical study confirmed the results obtained from the crossover study in essentially all measurements. Thus, the antioxidant and cardiovascular benefits of LifePak are supported by two independent well-designed, double-blind clinical studies.*

For additional clinical results, please refer to the following references:

- Smidt CR, Seidehamel RJ, Devaraj S, Jialal I. The Effects of a Nutritionally Complete Dietary Supplement (LifePak®) on Antioxidant Status and LDL-Oxidation in Healthy Non-Smokers. *FASEB Journal* 1999;13(4):A546.
- Over 1,000 clinical studies support the benefits of the ingredients in LifePak. For a complete list of references, please contact Pharmanex at 1-800-487-1000.

INGREDIENTS

LifePak provides 39 vitamins, minerals, trace elements, antioxidants, and phytonutrients, which are provided in two daily packets. For a detailed ingredient list call Pharmanex at 1-800-487-1000.

RECOMMENDED USE

As a dietary supplement, take the contents of one LifePak packet bid with water or food.

SAFETY

All individual nutrient levels in LifePak are documented to be safe and clinical studies showed no adverse effects due to LifePak supplementation. The daily amounts of all vitamins and minerals are well below the No-Observed Adverse Effect Levels (NOAEL) established by the Council for Responsible Nutrition (CRN) in 1997 and the Upper Limits (UL) established by the Food and Nutrition Board of the National Research Council. The other nutrients in LifePak, including the phytonutrients, are added in amounts that can be obtained from diets high in fruits and vegetables (5-10 servings/day) or other commonly consumed foods and beverages.

WARNINGS

Keep this product out of reach of children. Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six years of age. In case of accidental overdose, call a doctor or poison control center immediately. Consult a physician prior to use of taking a prescription medication. Discontinue use of this product 2 weeks prior to and after surgery.

HOW SUPPLIED

Each box provides 60 individual packets, or the equivalent of a one-month supply, and can be purchased from independent distributors and pharmacies.

PDR® entry for

TEGREEN 97™ (Pharmanex)

OTC

Standardized Green Tea Polyphenol Extract

250 mg capsules
Dietary Supplement

DESCRIPTION

Tegreen 97 is a standardized, caffeine-free polyphenol extract of the fresh leaves of the tea plant *Camellia sinensis*. The major components of Tegreen are polyphenols, which have proven free radical scavenging and antioxidant properties. The polyphenols with the most active antioxidant activity are the catechins, specifically epigallocatechin gallate (EGCg) and epigallocatechin (EGC).*

INGREDIENTS

Each 250 mg capsule of proprietary Tegreen 97 contains a 20:1 extract of green tea leaves (*Camellia sinensis*) standardized to a minimum 97% pure polyphenols including 162 mg catechins, of which 95 mg is EGCg, 37 mg is ECG, and 15 mg is EGC. Tegreen 97 is decaffeinated (<0.5 mg).

SCIENTIFIC SUPPORT

The ingestion of green tea polyphenols promotes general well-being by affecting a very broad spectrum of functions. In large-scale epidemiological studies in Asia (totaling more than 100,000 people for study periods up to 10 years), daily consumption of 4 or more cups of a green tea beverage was associated with significant overall health benefits (*Mitscher et al., Medicinal Res Rev 1997; 17: 327-365*). Even after adjustments were made for potential confounding factors including age, tobacco and alcohol use, and body weight such benefits were still evident.*

In addition to providing direct protection from the oxidative effects of potentially toxic free radicals, green tea polyphenols may also enhance the body's natural resistance to environmental toxins and stresses by increasing the activity of certain antioxidant and detoxifying enzymes, including glutathione peroxidase,

glutathione reductase, glutathione S-transferase, catalase, and quinone reductase in some cells and tissues. Supplementation with green tea polyphenols (especially the catechin EGCG) may help: (1) block the formation of toxic compounds, including nitrosamines (2) suppress the activation of free radicals (3) detoxify or trap free radicals (4) inhibit spontaneous and photo-enhanced lipid peroxidation (5) inhibit the enzyme urokinase.*

For additional clinical results, refer to the following references:

- Mitscher L, et al. Chemoprotection: A review of the potential therapeutic antioxidant properties of green tea (*Camillia sinensis*) and certain of its constituents. *Medicinal Research Reviews* 1997;17(4):327-365.
- Mitscher L, et al. Naturally occurring antimutagens and cytoprotective agents, biologically active natural products: agrochemicals and pharmaceuticals. CRC Press [In Press].
- Pillai S, et al (1999) "Antimutagenic/Antioxidant activity of green tea components and related compounds". *Journal of Environmental Pathology, Toxicology and Oncology* 1999;18(3):lead article.

RECOMMENDED USE

As a dietary supplement, take one 250 mg capsule qd with food. Each capsule provides the green tea polyphenols typically found in approximately 7 cups of high-quality brewed green tea.

SAFETY

Not known to be associated with any significant side effects or toxicity. Since Tegreen contains only trace amounts of caffeine (approximately 1-1.3 mg/capsule), it should not produce the stimulant caused by the consumption of caffeine-containing beverages.

WARNINGS

Tegreen has not been evaluated in children and should only be used by adults. Pregnant or breast feeding mothers should consult a physician prior to use. Consult a physician prior to use if taking anticoagulants, or other prescription medications. Discontinue use of this product 2 weeks prior to and after surgery.

HOW SUPPLIED

Tegreen capsules are supplied in 30 count packages, and can be purchased from independent distributors and pharmacies.

PDR® entry for

CORDYMAX Cs-4™

OTC (Pharmanex)

Cordyceps sinensis mushroom mycelia

525 mg capsules

Dietary Supplement

DESCRIPTION

CordyMax Cs-4 (Patent Pending) is a dietary supplement used to reduce symptoms of fatigue, and to promote vitality and overall well-being.* It is an exclusive fermentation product derived from the mycelia of the principal fungal strain (*Paecilomyces hepiali* Chen Cs-4) isolated from the renowned *Cordyceps sinensis* mushroom. CordyMax has been profiled extensively by chemical and pharmacological methods, and is recognized as having activity most similar to wild *Cordyceps sinensis* . For over two-thousand years, *Cordyceps sinensis* has remained the premier agent in the pharmacopoeia of traditional Chinese medicine to restore vitality and energy, and to serve as a potent tonic conducive to general health and normal aging concerns.*

SCIENTIFIC SUPPORT

In humans and animals, CordyMax substantially increases the serum levels of the enzyme superoxide dismutase (SOD). This enhancement of the enzyme's proven ability to scavenge the free radicals associated with age-related oxidative cellular damage may explain the traditional use of the mushroom as a dietary supplement to improve vitality, energy, and quality of life. Scientific studies also indicate that supplementation with CordyMax may (1) Reduce oxidative stress by scavenging oxygen-free radicals in mitochondria; (2) Promote efficient utilization of oxygen, increase VO₂ Max, and enhance lung function; (3) Elevate energy states (ATP) in organs; (3) Redistribute blood flow to essential organs; (4)

Maintain normal liver and kidney functions; (5) Improve exercise capacity and resistance to fatigue.*

For additional clinical results, please see the following references:

- Zhu JS, et al. The Scientific Rediscovery of an Ancient Chinese Herbal Medicine: Cordyceps sinensis Part I and II. J Alt Comp Med 1998;4(3):289-303 and 1998;4(4):429-457.
- Nicodemus KJ, et al. Supplementation with Cordyceps Cs-4 fermentation product promotes fat metabolism during prolonged exercise. Med Sci Sport Exercise 2001;33:S164.
- Xiao, Y., et al. "Increased Aerobic Capacity in Healthy Elderly Humans Given a Fermentation Product of Cordyceps Cs-4". Med Sci Sport Exercise 1999;31(5):S120.

INGREDIENTS

Each capsule of CordyMax CS-4 contains 525 mg of the fermentation product of mycelia (*Paecilomyces hepiali* Chen, Cs-4) isolated from the mushroom *Cordyceps sinensis* (Berk.) Sacc., and is scientifically standardized to contain a minimum of 0.14% adenosine and 5% mannitol (an indicatory of polysaccharide content).

RECOMMENDED USE

As a dietary supplement, take two 525 mg capsules bid or tid with water or food. Optimal results typically take 3 to 6 weeks.

SAFETY

With the exception of one case of allergic skin reaction, no other adverse reactions have been reported. During clinical trials in China, some subjects noted a mild sensation of thirst, and one subject noted slight nausea. All subjects considered these effects quite tolerable. No cases of CNS effects have been reported. No contraindications were identified based on Chinese human studies. CordyMax is non-mutagenic and non-teratogenic.

WARNINGS

CordyMax has not been evaluated in children and should only be used by adults. Pregnant and breast feeding mothers should consult a physician prior to use. Consult a physician prior to use if using anticoagulants, MAO inhibitors, or any other prescription medication.

HOW SUPPLIED

CordyMax capsules of 525 mg each are supplied in 120 count packages, and can be purchased from independent distributors and pharmacies.

PDR® entry for

REISHIMAX™ (Pharmanex)

OTC

Standardized Reishi Mushroom Extract

500 mg capsules

Dietary Supplement

DESCRIPTION

ReishiMax is a proprietary, standardized extract of Reishi (*Ganoderma lucidum*) mushroom. ReishiMax™ supports healthy immune system function by stimulating cell-mediated immunity with a proprietary standardized Reishi formula. ReishiMax is intended for adults who wish to maintain a healthy immune system; who smoke or who are frequently exposed to environmental pollutants; who do not get enough sleep; or who are under constant stress. *

In China, Reishi is a TCM herb of choice as a general tonic for promoting longevity, vitality and endurance, and for health preservation. As recorded in New Compilation of Materia Medica (y. 1757), Reishi "benefits heart and lung, nourishes the essence and vital energy, prevents from illness, and acts for millennia as a longevity-promoting herbal tonic." *

INGREDIENTS

ReishiMax is composed of Reishi fruiting bodies and cracked spores. The key active constituents found in Reishi include polysaccharides (beta -1,3-glucans) and triterpenes (ganoderic acids and others). Other ingredients naturally found in Reishi include nucleosides, fatty acids (oleic acid), and amino acids. The active ingredients in ReishiMax are standardized to 6% triterpenes and 13.5% polysaccharides. ReishiMax also contains a 1% extract of 100% cracked spores.

SCIENTIFIC SUPPORT

According to the results of animal and *in vitro* studies, ReishiMax has been demonstrated to stimulate the formation of antibodies, stimulate the ability of proliferation of immune cells, and modulate the functions of T cells. Ample amounts of data from animal and *in vitro* studies strongly support that Reishi extracts can enhance cell-mediated immunity by influencing lymphocytes, natural killer (NK) cells, tumor necrosis factor (TNF) and other cytokines, macrophages, and histamine release from mast cells, thus resulting in improved health benefits.

*

An unpublished comparative study recently conducted by the Medical Institute at National Taiwan University found that ReishiMax enhanced immune function in mice compared to placebo and the leading Reishi competitor in Taiwan (Chiang 2002, manuscript in preparation). After six weeks, ReishiMax increased serum immunoglobulins (IgG, IgM, IgA), increased proliferation of lymphocytes, and increased secretion of cytokines (IL-2, IL-5, IL-6) and IFN(gamma). *

In clinical studies, Reishi extracts have been shown to increase levels of T-cell counts, CD4/CD8 ratio, cytokine IL-2, complement C3 and immunoglobulin G, lower levels of T-suppressor cell counts, improve vigor and appetite, and shorten recovery time (Kupin 1992, Yang 1996). *

For additional clinical results, please see the following references:

- Kupin, V. (1992). A new biological response modifier-- *Ganoderma lucidum* -- and its application in oncology, in: *The 4th International Symposium on Ganoderma lucidum*, Hyatt Regency hotel, June 10, 1992, Seoul, Korea, Program and Abstracts, pp. 36-39.
- Yang QY, Wang, M. M. (1996). The anti-aging effects of *Ganoderma* essence, in: *1996 Taipei International Ganoderma Research Conference*, Taipei International Convention Center (TICC), August 15-15, 1996, Abstracts, Special Lecture.

SAFETY

ReishiMax is safe and well tolerated at the recommended dosage. In animal studies, Reishi has been shown to be non-carcinogenic, has not produced hepatic toxicity, and has not impaired growth or development. In high doses (1.5

to 1.9 grams/day), some people have experienced temporary symptoms of sleepiness, thirst, rashes, bloating, frequent urination, abnormal sweating, and loose stools.

WARNINGS

Keep out of reach of children. If you are pregnant or nursing, or taking a prescription medication, consult a physician before using this product. Consult a physician if you are concurrently using anticoagulants, receiving immunosuppressive therapies or have an immune disorder. Individuals with known fungal allergies should be cautious when taking Reishi. Discontinue use of this product 2 weeks prior to and after surgery.

RECOMMENDED USE

Take one to two capsules of ReishiMax with liquid at your morning and evening meals. For optimal health benefits, take one (1) capsule twice daily for health maintenance, and two (2) capsules twice daily for immune modulation.

HOW SUPPLIED

ReishiMax is supplied in a 15-30 day supply of 60 capsules. Each capsule contains 495 mg of standardized Reishi mushroom extract and 5 mg of Reishi cracked spores.

PDR® entry for

CORTITROL™

OTC (Pharmanex)

Stress Control Formula

348 mg capsules

Dietary Supplement

DESCRIPTION

Cortitrol Stress Control Formula™ is a dietary supplement developed and manufactured by Pharmanex, LLC, to help the body modulate healthy levels of cortisol.* Cortitrol is a patent-pending cortisol-controlling dietary supplement that combines natural ingredients that have been scientifically shown to have direct cortisol-balancing effects. Ingredients included in Pharmanex Cortitrol that may have cortisol-lowering effects include magnolia bark (*Magnolia officinalis*), epimedium (*Epimedium koreanum*), theanine, beta sitosterol and phosphatidylserine.*

SCIENTIFIC SUPPORT

In humans and animals, the ingredients in Cortitrol have been shown to address various aspects of cortisol control.* Cortitrol helps provide enhanced feelings of well-being and control in response to stressful situations. Improved performance and increased vigor throughout the day are achieved by the documented anxiolytic effects of magnolia bark and the relaxation effects of theanine.* Cortitrol helps support weight maintenance efforts and allows better mental concentration and focus through the natural cortisol-controlling effects of theanine, epimedium, beta sitosterol and phosphatidylserine.*

For additional clinical results, please see the following references:

- Bouic PJ, Clark A, Lamprecht J, Freestone M, Pool EJ, Liebenberg RW, Kotze D, van Jaarsveld PP. The effects of B-sitosterol and B-sitosterol glucoside mixture on selected immune parameters of marathon runners: inhibition of post marathon immune suppression and inflammation. *Int J Sports Med.* 1999 May;20(4):258-62.
- Monteleone P, Maj M, Beinat L, Natale M, Kemali D. Blunting by chronic phosphatidylserine administration of the stress-induced activation of the hypothalamo-pituitary-adrenal axis in healthy men. *Eur J Clin Pharmacol.* 1992;42(4):385-8.
- Maruyama Y, Kuribara H, Kishi E, Weintraub ST, Ito Y. Confirmation of the anxiolytic-like effect of dihydrohonokiol following behavioural and biochemical assessments. *J Pharm Pharmacol.* 2001 May;53(5):721-5.
- Epel EE, Moyer AE, Martin CD, Macary S, Cummings N, Rodin J, Rebuffe-Scrive M. Stress-induced cortisol, mood, and fat distribution in men. *Obes Res.* 1999 Jan;7(1):9-15.

- Bjorntorp P. Do stress reactions cause abdominal obesity and comorbidities? *Obes Rev.* 2001 May;2(2):73-86.

INGREDIENTS

Each capsule of Cortitrol contains 133 mg of Magnolia bark (*Magnolia officinalis*), standardized to 2% Honokiol - a constituent with known anxiolytic properties, 100 mg Epimedium (*Epimedium koreanum*) Water Extract 6:1, 66.7 mg L-Theanine (from *Camellia sinensis*) Extract 70:1 (TheaPure™), 40 mg Beta Sitosterol, and 8.3 mg Phosphatidylserine.

RECOMMENDED USE

As a dietary supplement, take two to three 348 mg capsules daily. Take two 348 mg capsules with evening meal. For optimal results take an additional 348 mg capsule with your morning meal.

SAFETY

Cortitrol is safe and well tolerated at the recommended dosage. L-theanine has been approved in Japan for unlimited use in all foods, except infant foods, after favorable toxicology studies. There are no limitations to duration of administration or known adverse drug interactions.

WARNINGS

Cortitrol has not been evaluated in children and should only be used by adults. Pregnant and breast feeding mothers should consult a physician prior to use. Consult a physician prior to use if using any prescription medication. Because Cortitrol is indicated for stress relief, consult a physician if you are taking prescription "anti-stress" medications such as anxiolytics, sedatives, or hypnotics. Consult a physician if you are taking other CNS depressants, tricyclic antidepressants, anti-epileptics, muscle relaxants, anticoagulants, corticosteroids and quinalone antibiotics. Use of L-theanine concomitantly with chemotherapeutic agents must be done under medical supervision. L-theanine may enhance the

effects of doxorubicin, idarubicin, adriamycin, and picarubicin and may ameliorate some of their side effects. This supplement should be discontinued two weeks prior to surgery.

HOW SUPPLIED

Cortitrol capsules of 348 mg each are supplied in 60 count packages, and can be purchased from independent distributors and pharmacies.

STORAGE/SHELF LIFE

For all Pharmanex dietary supplements:

Storage: Store in a dry, cool place. Avoid excessive heat. Protect from light.

Shelf Life: Expiration date is imprinted on box and bottle.

EDUCATIONAL MATERIALS

For more information, including scientific references and scientific support papers for Pharmanex Healthcare Products: Call toll free 1-800-487-1000, Monday - Friday, 8 am to 5 pm, MST. Website: www.pharmanex.com

***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.**