

TEGREEN 97®

HEALTHCARE PROFESSIONAL PRODUCT GUIDE

Tegreen97 is a dietary supplement being sold by Pharmanex to support the immune system in the presence of pollution, stress, and toxins. This is an educational publication provided to help licensed health care practitioners understand the science upon which Tegreen97 is based and the mechanism of action by which Tegreen97 works. This pamphlet should not be used to sell Tegreen97, and it should be distributed only to licensed health care practitioners.

SUMMARY

Tea is one of the world's most popular beverages, second only to water. The health-promoting benefits of green tea have been recognized in China for thousands of years. However, it is only recently that subtle but significant differences have been noted between black and green tea in terms of deriving therapeutic benefits from tea drinking. Evidence is accumulating that the method of preparing tea leaves plays a pivotal role in preserving the ingredients that are necessary to create tea with health benefits, the green tea polyphenols.* Recent scientific evidence supports the hypothesis that urokinase and free radicals can be influenced by polyphenols, especially epigallocatechin-3-gallate (EGCG).* This review outlines current information on the chemistry and biological activity of green tea together with laboratory and epidemiological studies of its potential health benefits. It also further describes Pharmanex's proprietary decaffeinated Tegreen97, which contains consistent and high levels of medicinal polyphenols.

WHAT IS TEGREEN 97?

Tea is one of the most popular beverages worldwide, with an average daily consumption estimated at close to one 6 fl oz cup (Asian-size cup) per person,¹ although there is a large geographical variation in consumption rates. While most of the world's tea is consumed as black tea, the commercial manufacture of black tea robs this beverage of polyphenols. In contrast, green tea is prepared so as to minimize polyphenol oxidation, thus preserving its polyphenol content and medicinal properties.*

Although green and black tea are derived from the same plant (*Camellia sinensis*), there are significant differences in their preparation. Black tea (more common in the western world) is withered, rolled, fermented and dried for curing. Through this flavor-enhancing fermentation process, the bioactive polyphenols of the fresh leaf are oxidized, and black tea loses its full complement of beneficial polyphenols.

Green tea, on the other hand, is prepared from lightly steamed and dried leaves of the tea plant. The steaming process inactivates the enzymes responsible for oxidation, leaving the polyphenol content intact and resulting in a product with a chemical composition very similar to that of the fresh leaf.

Tegreen97 is prepared by proprietary methods under conditions of strict quality control to ensure a high concentration of active polyphenols. A full 97% of the important polyphenols of green tea are preserved in Tegreen97, making this the preparation of green tea with the highest concentration of polyphenols available in a dietary supplement.*

TeGreen97 provides 160 mg of green tea catechins per capsule. Analytical methods have recently improved with the ability to measure individual catechins by HPLC methods. A highly credible recent USDA study determined by HPLC that one Asian size (6 fl oz) cup of traditionally brewed

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(1.5 grams of tea leaves per cup) green tea provides about 22 mg of total catechins, half of which is EGCg.⁵³ Based on this new finding, one capsule of Tegreen97 is equivalent to approximately seven Asian-size cups of green tea.* This is a significant finding, because studies demonstrate the daily consumption of four cups of green tea provides significant benefits to overall health.*

MECHANISM OF ACTION

Increasing evidence suggests that the therapeutic effects of green tea are mediated by tea polyphenols.* The mechanisms of tea polyphenols include antioxidant activity, inhibition of nitrosation reactions, and inhibition of urokinase activity.*

Antioxidant Activities: Powerful antioxidant properties, equivalent to those of vitamin E and greater than vitamin C,^{2 3 4} are conferred by the multiple hydroxyl group of the polyphenols, which are readily oxidized to give the corresponding O-quinones.* As a result, green tea polyphenols are effective scavengers of active oxygen species such as a wide variety of biomolecules, primarily DNA and membrane lipids.^{5*} Since the generation of reactive oxygen species is catalyzed by metal ions, the metal chelating properties of the tea polyphenols also contribute to reducing the levels of oxygen free radicals in the cell.

Inhibition of Nitrosation Reactions: Endogenous nitrosation of nitrogenous compounds can lead to the formation of N-nitroso compounds. Green tea has been shown to inhibit nitrosation in vitro by reacting with nitrosating species.^{6 *}

Inhibition of Urokinase Activity: Urokinase, a proteolytic enzyme naturally found in the body, may be inhibited by EGCG in the extracellular matrix.^{7 *}

SCIENTIFIC SUPPORT

Pre-Clinical Studies

Numerous published scientific studies using green tea extract, known as Xin Nao Jian in Asia, suggest that the ingestion of green tea polyphenols provides a very broad spectrum of beneficial physiological functions related to the promotion of general well-being.* In addition, the proprietary extract found in Tegreen 97 has been shown to exhibit many of these health-promoting benefits.* Detailed information on the benefits of green tea has been published in a review paper by Mitscher et al.⁴ In large scale epidemiological studies in Asia (totaling more than 100,000 people for study periods up to 10 years), daily consumption of four or more 6 fl oz cups (Asian-size cups) of a green tea beverage has been associated with significant overall health maintenance of subjects, even after adjustments were made for age, smoking, alcohol consumption, and relative body weight.

Recent studies have demonstrated that the polyphenols in green tea, particularly the catechin component, offer potent antioxidant activity through the scavenging of free radicals.*^{49 50} Free radicals, which are involved in the damage of cellular constituents, including DNA, are often the result of exposure to dietary, occupational and environmental toxins. Upon ingestion, concentrations of green tea polyphenols can be easily detected in blood, urine and feces, suggesting that polyphenols are orally bioavailable (absorbed through the gastrointestinal tract).

CLINICAL STUDIES

Antioxidant Protection

In a recent study at Kansas University, researchers found new evidence confirming that a compound in a green tea supplement Tegreen97 provides stronger free radical damage protection of the genetic

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material in cells (DNA), than the well-known antioxidants vitamins E and C, and the antioxidant compound found in red wine.** (**based on in vitro studies)

This yet to be published research is the first of its kind to use the Ames test to determine the effectiveness of green tea (using Tegreen97) as an antioxidant to protect against DNA degradation. Using the Ames test, EGCg was added to DNA samples challenged with peroxide, a recognized powerful free radical. The research found EGCg to be a powerful antioxidant, offering 68% protection from DNA damage. The level of protection of DNA samples in the presence of Tegreen97 was significantly higher when compared with a control group of DNA without Tegreen97.

This is the first side-by-side antioxidant study comparing the protective power of epigallocatechin gallate (EGCg) against that of vitamins E and C, red wine, and other teas. Using equivalent concentrations in the study, vitamin E was found to be much less protective against damaged cell growth than EGCg or Tegreen97, while vitamin C showed little protective activity at the same concentration. Specifically, EGCg, as found in Tegreen97, was approximately 100 times more effective than vitamin C, 25 times more effective than vitamin E, and nearly twice as effective as the antioxidant compound in red wine at protecting cells. *

Numerous experiments and studies indicate that green tea polyphenols, especially EGCg, may help:

- block the formation of some potentially toxic compounds, such as nitrosamines, which are formed from the ingestion of some cured meats*
- suppress the activation of free radicals*
- detoxify or trap free radicals*
- inhibit spontaneous and photo-enhanced lipid peroxidation*
- increase the activity of natural antioxidant and detoxifying enzymes, e.g., glutathione peroxidase, and catalase*

The association between green tea consumption and cancer incidence was studied in a prospective cohort study of a Japanese population. 51 Imai et al., surveyed 8,552 individuals, over 40 years of age, on their living habits, including daily consumption of green tea. They found a negative association between green tea consumption and cancer incidence, especially among females drinking more than 10 cups a day. This epidemiological study showed that green tea has a potentially preventive effect against DNA damage among humans, but in vivo research is still needed.

A recent study evaluated the chemopreventive effect of green tea against cigarette smoke-induced mutations (SCE) in humans. 52 Chemopreventive effects of green tea were examined in 52 clinically healthy male subjects between 20-51 years of age. The frequencies of sister-chromatid exchange (SCE) in mitogen-stimulated peripheral lymphocytes, from blood samples, in each experimental group were determined and statistically analyzed. The analysis found that the frequency of SCE in smokers who consumed green tea ($7.94 + 0.31$) was comparable to that of non-smokers, implying that green tea can block the cigarette-induced increase in SCE frequency.

Skin and Dental Health

Although sunscreen should always be used, antioxidant supplementation may offer some protective benefits to the skin from free radical damage and the effects of ultraviolet rays. Among the polyphenols that are antioxidants in green tea, EGCg and ECG show the strongest effect in reducing collagenase activity - an enzyme that breaks down collagen.* This reduced enzyme activity may help promote healthy collagen and elastin integrity.* In part, EGCg and ECG do this by promoting a

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realignment of these proteins to a more youthful form.* Supplementing the diet with antioxidants, such as green tea's polyphenols, may lessen the effects of age-related skin damage.*

Researchers from the Department of Clinical Pathology at the Nihon University School of Dentistry in Japan investigated the ability of liquid green tea extracts for promoting dental health in laboratory experiments and animals studies. Green tea inhibits the growth of *S. mutans* and other bacteria associated with the normal deposit of unwanted or unhealthy materials that may build up on the surface of teeth after eating certain foods. While more research is needed, regular consumption of moderate amounts of green tea (and EGCg) may help keep teeth as healthy as possible.*

PROPRIETARY PROCESSING

Green tea characteristics vary widely according to growing region, altitude, climate and processing techniques. Pharmanex adheres to the time-honored tradition of using only the finest leaf buds and young leaves of tea plants cultivated in Zhejiang Province, the number one tea-producing region in China producing some of the highest quality tea in the world. The proprietary extraction process Pharmanex employs is designed to preserve the beneficial green tea components by maximizing the concentration of the naturally occurring polyphenols, while virtually eliminating caffeine.

TEGREEN 97 POLYPHENOLIC PROFILE

Tegreen97 provides the most concentrated levels of green tea polyphenols available in a dietary supplement, and is carefully standardized through advanced technologies and proprietary methods. (See HPLC chart) Other catechins analyzed: DL-Catechin (DL-C); Epicatechin (EC); Gallocatechin gallate (GCG). Catechins (especially EGCg) appear to have the greatest capacity to quench free radicals.* Extract also includes: chlorophyll, lignans, proanthocyanidins and phenolic acids.

SIDE EFFECTS

The polyphenol content of green tea is not known to be associated with any significant side effects or toxicity. In a long term toxicity study, an extract solution of Tegreen97^a was intragastrically perfused into rats at 21, 107 and 214 times the recommended adult daily dose for four months. At the end of four months, the rats showed no abnormalities in general signs, behavior, food intake, feces, and weight increases. Pathological examinations at the end of four months showed normal organ weight and morphology of heart, liver, kidney, spleen, lung, stomach, duodenum, adrenal gland, and testicle or ovary.

Since Tegreen97 is labeled caffeine-free, it should not produce the stimulant effect caused by the consumption of caffeine-containing beverages in some people. It is recommended that Tegreen97 be taken with food to minimize any possibility of gastric discomfort.

SAFETY AND TOXICOLOGY

There is little quantitative information related to the toxicity of green tea catechins. Evidence derived from epidemiological data indicate that long-term consumption of 10 or more cups per day is without adverse effects and may be associated with significant health benefits.⁴ There is no evidence of long-term or short-term toxicity of green tea extracts.

DRUG INTERACTIONS

No drug interactions specific for green tea polyphenols have been identified. However, EGCg has been shown to inhibit collagen-induced platelet aggregation, so individuals taking aspirin or other anticoagulant substances on a daily basis should consult with a physician.

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DIRECTIONS FOR USE

As a dietary supplement, take one capsule daily with water and food. The polyphenol content in one capsule of Tegreen97 is equivalent to approximately seven cups of traditionally brewed green tea... without the caffeine. Tegreen97 should be taken regularly for optimal health benefits.

HOW SUPPLIED

Tegreen97 capsules (250 mg each) are supplied in a one-month supply of 30 capsules. Clear gelatin capsules are USP quality and are designed to disintegrate within 30 minutes after ingestion.

STORAGE

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

SHELF LIFE

Expiration date and lot code numbers are imprinted on the bottom of the box or bottle.

WARNINGS

Keep out of reach of children. If you are pregnant or nursing, please consult a healthcare professional before taking this product.

INGREDIENTS IN TEGREEN97

Each 250 mg capsule of proprietary Tegreen97 contains a 20:1 extract of green tea leaves (*Camellia sinensis*) standardized to minimum of 97% pure polyphenols including 3162 mg of catechins of which ≥ 95 mg is EGCg. Tegreen97 is caffeine-free (<0.5 mg).

DO NOT USE IF...

- * You are taking aspirin or other anticoagulant substances on a daily basis;
- * You are lactating, in view of evidence that green tea may interfere with iron metabolism in infants.⁸

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