Sensoril® - A Patented Extract that Reduces Stress and Enhances Sleep

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STRUCTURE/FUNCTION CLAIMS:

- Helps increase resistance to fatigue, stress and tension*
- Anti-stress formula promotes emotional well-being*
- Helps counteract the negative effects of stress*
- Helps the body cope with stress*

* 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.

CONSUMERS DEMAND PRODUCTS THAT ENHANCE THE BODY'S ABILITY TO COPE WITH STRESS

Stress has become increasingly commonplace in today's fast-paced, hectic world, affecting the health and well-being of millions of people and costing the U.S. economy billions of dollars as a result of increased healthcare costs and lost worker productivity. In fact, because stress is so pervasive in people's lives, stress reduction has become the number one lifestyle and health issue for consumers according to *Food Technology* magazine. Stress is the body's response to real or imagined emotional or physical threats that cause it to become unbalanced. Sources of stress can vary from the relatively benign such as keeping up with day-to-day responsibilities to more acute causes such as loss of a job, divorce, or financial problems.

No matter the cause, the body responds to stress in a similar manner. This stress response, also known as the "fight or flight" response, is a series of physiological changes that prepares the body to either confront a stressor or escape from it and then bring about a return to homeostasis or balance. In the short-term, the stress response can be an asset, enhancing a person's ability to deal with life's changing circumstances. But if a person is subject to repeated stress over an extended period, the body gradually loses its ability to cope, resulting in the breakdown of vital functions and a decline in health and well-being. It has been estimated that chronic stress is responsible for causing or complicating over 90% of diseases that affect the body. Because chronic stress has become so rampant today, consumers are increasingly seeking novel, scientifically proven nutritional products that reduce stress-related symptoms while improving mood. Nutragenesis now sells a superior, stress-inhibiting nutraceutical under the tradename Sensoril® to satisfy this customer demand.

SENSORIL® - A NOVEL, SCIENTIFICALLY-PROVEN, STRESS-REDUCING NUTRACEUTICAL

Sensoril® is a multi-patented, standardized extract of Ashwagandha *(Withania somnifera)*, a plant grown in India that is revered for its ability to balance, energize, rejuvenate, and revitalize. Sensoril's stress-reducing characteristics result from unique bioactive compounds that are extracted from specially grown Ashwagandha roots and leaves in a patented, water-based process. These bioactives give Sensoril® adaptogenic properties. Adaptogens are a small group of plants and mushrooms that energize the body, increase its ability to resist and recover from stress, and stimulate an overall feeling of balance and normalization. Although adaptogens such as Ashwagandha, Indian Gooseberry, Reishi mushroom, and Cordyceps mushroom have been used as stress-reducers and revitalizers for thousands of years in Ayurvedic medicine and countries of the East, the concept of adaptogenic relief from stress is relatively new to the West. As an adaptogen, Sensoril® is unique in that it provides long-lasting relief from symptoms of stress while improving mood when taken as a tonic on a daily basis without any negative side effects.

THE STRESS RESPONSE RAISES LEVELS OF SERUM CORTISOL

When the body is stressed, normal homeostasis in the body is disrupted which causes a series of physiological reactions along the hypothalamus-pituitary-adrenal (HPA) axis. In response to a stressor, neuroendocrine cells of the hypothalamus (a component of the brain) release corticotropin-releasing hormone (CRH). CRH travels to the nearby pituitary gland and stimulates it to release adrenocorticotropic hormone (ACTH). ACTH, in turn, travels through the blood until it reaches the adrenal glands which sit atop each kidney. ACTH stimulates the release into the blood of catecholamine hormones like adrenaline as well as corticosteroid hormones like cortisol. These adrenal hormones are responsible for producing stress-related symptoms that prepare the body for intense physical and mental activity associated with the "fight or flight" response. Adrenaline acts primarily in response to short-term stress while cortisol produces symptoms associated with both short-term and chronic stress.

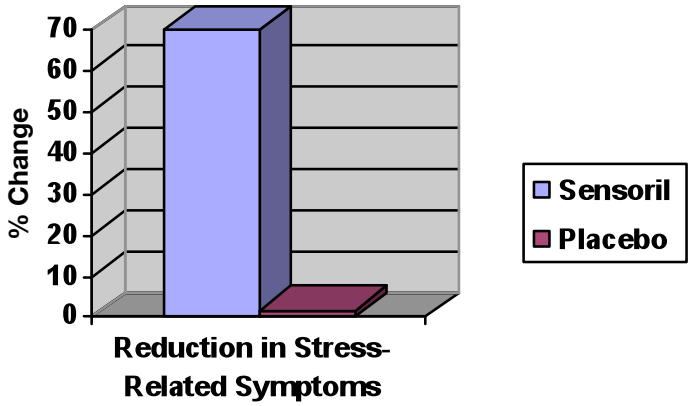
HIGH CORTISOL LEVELS PRODUCE SYMPTOMS OF CHRONIC STRESS

When a stressor leads to increased cortisol levels in the blood, the result is rapid changes in a host of body functions. Breathing and heart rates increase and blood vessels in muscles and the brain dilate to optimize oxygen delivery to those organs while the activity of non-emergency bodily process such as digestive organs is suppressed. Energy stores are mobilized, leading to higher blood glucose levels. The immune system is also suppressed while the body concentrates its resources elsewhere. If cortisol levels remain high for an extended period, a wide range of symptoms can occur including: irritability and anxiety, insomnia, inability to concentrate, fatigue, sweating, headaches and muscle pain, gastrointestinal problems such as ulcers, sexual problems, and heart palpitations. These problems can lead to decreased health and well-being, can foster harmful coping behaviors like alcoholism and drug addiction, and may ultimately contribute to such chronic illnesses as diabetes, high blood pressure, coronary heart disease, stroke, cancer, and lung ailments if not addressed.

SENSORIL® RELIEVES SYMPTOMS OF CHRONIC STRESS

Sensoril® has a unique ability to relieve symptoms of chronic stress and bring the body back into its natural balance. This was confirmed in a double-blind, placebo-controlled human clinical trial in which subjects taking Sensoril® at the recommended dosage of 250 mg per day had a 69.9% reduction in an overall measure of stress-related symptoms (Figure 1). These subjects also experienced significant reductions in individual symptoms of stress including: irritability, anxiety, insomnia, inability to concentrate, fatigue, sweating, headaches and muscle pain, and heart palpitations. In contrast, the placebo group saw no significant change in any of these symptoms for the duration of the study. Subjects taking Sensoril® had been subject to high levels of chronic stress prior to initiation of the study. As a result of Sensoril™ treatment, they experienced a substantial improvement in their mood.

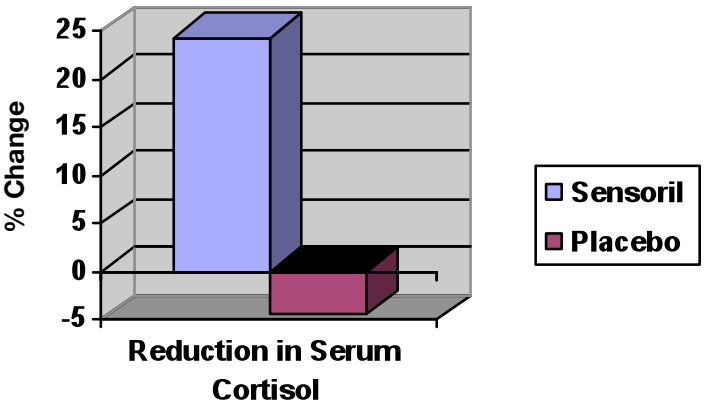
Figure 1. Percent Reduction in Stress-Related Symptoms in Subjects Receiving Sensoril® Compared to a Placebo.



SENSORIL® REDUCES SERUM CORTISOL LEVELS

Sensoril' ability to dramatically reduce stress-related symptoms and improve mood stems from its novel mechanism of action which mimics the activity of corticosteroid hormones that bring about the relaxation response. This naturally occurring process lowers serum cortisol levels after short-term stress to return the body to homeostasis. When stress is chronic, however, levels of these corticosteroids are insufficient to bring the body back into balance so cortisol levels remain high for extended periods. The glycowithanolide bioactives in Sensoril® are a class of steroidal lactones that structurally resemble these "deactivating" corticosteroids. This allows Sensoril® to boosts the body's ability to bring about homeostasis by lowering serum cortisol levels that are elevated due to chronic stress. In the same double-blind, placebo-controlled human clinical trial mentioned previously, Sensoril® treatment resulted in a 24.2% reduction in serum cortisol levels for subjects taking it at the recommended dosage of 250 mg/day (Figure 2).

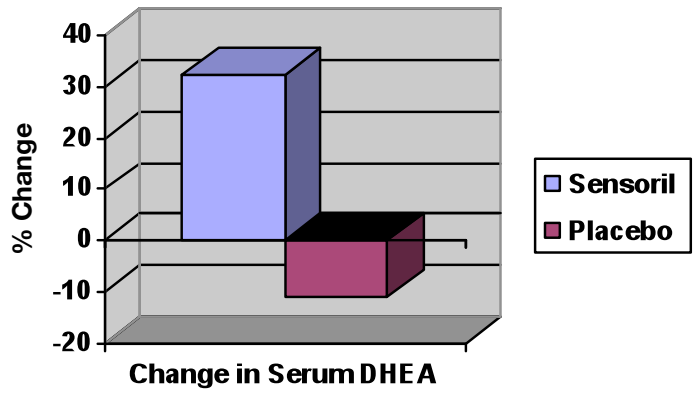
Figure 2. Percent Reduction in the Level of Serum Cortisol in Subjects Receiving Sensoril® Compared to a Placebo.



SENSORIL® RAISES SERUM DHEA LEVELS

Chronic stress not only leads to elevated serum cortisol levels, it also reduces the level of another corticosteroid produced by the adrenal glands, dehyroepiandrosterone (DHEA). DHEA is an important energizing hormone that competes for the same receptors as cortisol in the body, thereby balancing its effects. With less DHEA in someone who is chronically stressed, not only do they experience more fatigue than a non-stressed individual, their stress-related symptoms are also amplified because more receptors are free to bind cortisol. Sensoril® reverses this effect by raising serum DHEA levels. In the same double-blind, placebo-controlled human clinical trial, subjects taking Sensoril® at the recommended dosage of 250 mg/day had a 32.2% increase in serum DHEA levels (Figure 3). The combination of higher DHEA levels and lower cortisol levels in these subjects contributed to the reduction in fatigue and other stress-related symptoms the subjects experienced.

Figure 3. Percent Change in the Level of DHEA in Subjects Receiving Sensoril® Compared to a Placebo.



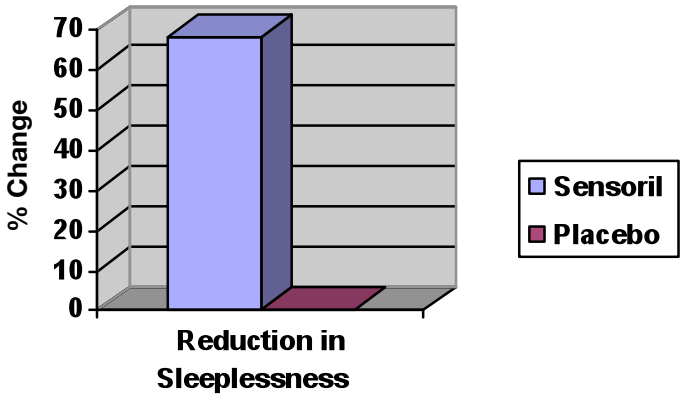
STRESS BRINGS ABOUT A CHANGE IN SLEEPING PATTERNS

A critical part of maintaining superior health and well-being is getting a good night's sleep. Sleep allows the body to rest and recover from the previous day's activities, including physical repair and mental recharge, in order to get ready for the next day's events. Sleep researchers have discovered that lack of adequate sleep leads to problems with concentration, learning, memory, immune function, and mood regulation, as well as accelerated aging. Over the long-term, inadequate sleep can contribute to many physiological problems including mental illness, cardiovascular disease, metabolic and hormone disregulations (like obesity, diabetes, and hypertension), and increased susceptibility to infections. Stress often leads to sleep problems because the body's stress response has evolved as a way for the body to prepare itself for either confronting a stressor ("fight") or fleeing from it ("flight"), both of which are impossible to do while sleeping. In a stressful situation, the brain is stimulated to remain awake, not get drowsy, and the body is in a heightened physical state, not calm and relaxed, making restful sleep difficult to attain. This translates into, for example, stressed individuals going to bed but staying up thinking about all the things that are worrying them.

SENSORIL® IMPROVES SLEEPING HABITS BY REDUCING SERUM CORTISOL LEVELS

Cortisol levels naturally rise and fall in a 24-hour period as part of a person's circadian rhythm. High levels in early morning wake the body from slumber. Low levels in the evening allow a person to fall asleep in response to rising levels of melatonin, a sleep-inducing hormone. Sleep is more difficult to achieve for chronically stressed people because this hormonal cycle is disrupted when serum cortisol levels remain elevated in the evening hours, restricting the ability of melatonin to induce sleep. By lowering serum cortisol levels, Sensoril® brings about a return to a healthy circadian rhythm and more restful nighttime sleep. The ability of Sensoril® to enhance sleep was confirmed in the double-blind, placebo-controlled human clinical trial mentioned previously. Subjects taking Sensoril® at the recommended dosage of 250 mg/day had a 68% reduction in sleeplessness

Figure 4. Percent Reduction in Sleeplessness in Subjects Receiving Sensoril® Compared to a Placebo.



SENSORIL'S ADAPTOGENIC PROPERTIES ENHANCE BOTH ENERGY AND SLEEP

Consumers are often under the impression that a product either enhances sleep while causing lethargy or energizes the body while preventing sleep. Sensoril's ability to enhance both nighttime sleep and daytime energy occurs because it has a different mechanism of action than regular sleep aids and energy products.

Sensoril, with its multifunctional, adaptogenic properties, brings the body into homeostasis and restores a normal circadian rhythm. This energizes the body because serum DHEA levels become elevated and also enhances sleep because the return to a normal circadian rhythm allows melatonin to induce drowsiness in the evening. Healthy energy such as that provided by Sensoril® does not eliminate the need for sleep, it operates in tandem with it. Similarly, a good night's sleep that results from the body returning to a healthy hormonal state, can lead to greater energy the next day.

This differs dramatically from most sleep aid and energy products which rely on mechanisms of action that short-circuit the body's normal circadian rhythm in order to produce an effect. Sleep aids that rely on chemicals that mimic or enhance levels of melatonin, GABA, or other sleep inducers, cause drowsiness regardless of the time of day and make a person lethargic. Similarly, the vast majority of energy products contain caffeine or other chemicals that mimic central nervous system stimulants to elicit a short-term "high" that initiates the "fight or flight response" but make sleep difficult to impossible. By disrupting the body's natural rhythm, these products also produce harmful side effects that restrict their use to only short periods. In contrast, Sensoril® restores the body's natural balance and does not produce any side effects, allowing its use for extended periods.

SENSORIL® - A SUPERIOR NUTRACEUTICAL THAT RELIEVES CHRONIC STRESS AND IMPROVES SLEEP

Scientifically proven Sensoril® reduces stress-related symptoms and improves mood in people who suffer from the debilitating effects of chronic stress. Sensoril's powerful stress-reducing properties result from its ability to foster a healthy hormone balance in the body, particularly by reducing levels of serum cortisol and raising levels of serum DHEA. In this way, Sensoril® boosts the body's ability to return to a state of normal equilibrium after stress has disrupted homeostasis. Because of these outstanding properties, Sensoril® is the superior choice for dietary supplement, food and beverage manufacturers looking to develop new anti-stress products for consumers who seek assistance in coping with the increasing instances of overwhelming stress they experience in their daily lives. ■

— Dr. Abedon received his M.S. and PhD in plant genetics from the University of Wisconsin-Madison and a B.S. in Biochemistry from the University of Massachusetts-Amherst. Dr. Abedon may be contacted through NutraGenesis at 802-257-5345, or bruce@nutragenesis.com.