



## **GABAdone™ Product Information for Sleep Disorders Associated with Anxiety**

### **Medical Food Classification**

*(\*References begin in Background Section p. 7)*

GABAdone is a Medical Food formulated to be used by practicing physicians for the nutritional management of certain sleep disorders. GABAdone provides the amino acids that are precursors to the neurotransmitters that induce and maintain sleep.

Under the regulations of the Food and Drug Administration, Medical Foods may only be used when a patient is under the active and ongoing care of a physician. Medical Foods are used for the dietary management of disease states with known nutritional requirements. Medical Foods must contain ingredients from the human diet that are designated as “generally recognized as safe” (GRAS). Medical Foods cannot be sold directly to patients without physician supervision.

### **Distinctive Nutritional Requirements**

A critical component of the definition of Medical Foods is that products are formulated to address distinctive nutritional requirements as medically determined. Medical Foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. Medical Foods and their distinctive nutritional requirements are intended to be used by a patient who is under ongoing medical supervision.

FDA scientists have proposed a physiologic definition of distinctive nutritional requirements as follows:

“the dietary management of patients with specific diseases requires, in some instances, the ability to meet nutritional requirements that differ substantially from the needs of healthy persons. For example, in establishing the recommended dietary allowances for general, healthy population, the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences, recognized that different or distinctive physiologic requirements may exist for certain persons with special nutritional needs arising from metabolic disorders, chronic diseases, injuries, premature birth, other medical conditions and drug therapies”.

**“Thus, the distinctive nutritional needs associated with a disease reflect the total amount needed by a healthy person to support life or maintain homeostasis, adjusted for the distinctive changes in the nutritional needs of the patient as a result of the effects of the disease process on absorption, metabolism and excretion.”** It was also proposed that in patients with certain disease states who respond to nutritional therapies, a physiologic requirement for the nutrient is assumed to exist.

## **Nutritional Requirements Associated with Sleep Disorders**

Patients with sleep disorders frequently exhibit increased nutritional requirements for tryptophan, choline, and GABA. Testing in patients with sleep disorders has revealed reduced blood levels of serotonin and 5-hydroxytryptophan resulting in a tryptophan deficiency that interferes with normal sleep patterns. In addition, there is an alteration of tryptophan metabolism in patients with certain sleep disorders. Choline deficiencies have been associated with certain sleep apnea syndromes.

### **Indications for Use**

1. Difficulty in falling asleep
2. Difficulty in maintaining sleep
3. Difficulty in falling back to sleep after awakening in the night.
4. Waking up feeling tired
5. Snoring

### **Neurotransmitter Production in the Human Body by *GABA*done**

1. Choline produces acetylcholine
2. 5-hydroxytryptophan produces serotonin
3. Glutamic acid produces glutamate
4. GABA stimulates GABA receptors

### **Targeted Cellular Technology™**

This unique five-component process allows milligram quantities of neurotransmitter precursors to enter the cells and produce the required neurotransmitters. This process includes a neurotransmitter precursor, an uptake stimulator, a neuron activator, an adenosine brake inhibitor, and an attenuation releaser. Previous attempts to use neurotransmitter precursors have required much larger quantities of the precursors to elicit a therapeutic effect, making it functionally impossible for a patient to ingest large, gram quantities of a precursor agent on a daily basis. The use of the *Targeted Cellular Technology* process also prevents the development of tolerance. Unlike pharmaceutical agents that lose their effectiveness in a relatively short period, GABAdone maintains its effectiveness and does not attenuate.

### **GABAdone Ingredients:**

Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, GABA, Grape Seed Extract, Griffonia Extract, Whey Protein, Valerian Extract, Ginkgo Biloba and Cocoa.

## **Targeted Cellular Technology and GABAdone**

GABAdone is designed to produce the neurotransmitters serotonin and acetylcholine. Serotonin is the neurotransmitter that initiates sleep. Acetylcholine is the neurotransmitter that maintains Delta IV-V deep sleep and facilitates REM sleep. GABA is the neurotransmitter that activates the GABA-receptors and helps maintain restorative sleep. GABAdone is designed to provide serotonin and acetylcholine precursors to enhance the production of the serotonin and acetylcholine neurotransmitters while providing GABA directly.

## **GABAdone and Clinical Testing**

Physiologic testing of autonomic nervous system function has been performed on individuals taking GABAdone. Patients without sleep disorders display normal parasympathetic activation that results in restorative sleep and reduction in snoring. Normal parasympathetic activation has been measured by Heart Rate Variability analysis. Patients with sleep disorders display reduced parasympathetic activity as measured by Heart Rate Variability analysis of 24-hour electrocardiogram. Patients with known sleep disorders taking GABAdone have shown improvement in parasympathetic activation as measured by HRV analysis. There have been two open label trials of GABAdone for sleep induction and maintenance, and one for reducing the frequency of snoring. There have been eight open label trials of GABAdone in patients who awaken in the middle of the night.

One double-blind placebo-controlled randomized clinical trial has been performed in patients with sleep disorders using GABAdone.

## **GABAdone Validation, and Clinical Testing**

Validation of Medical Food products is based on a physiologic response to the administration of the nutrient. If the administration of arginine increases arginine blood levels and increases nitric oxide production then a nutrient requirement for arginine is established. If the administration of arginine results in the increase of nitric oxide production in the lung and the FEV1 increases, a nutrient requirement for arginine is established. If in a sleep disorder, tryptophan administration increases serotonin production and sleep architecture improves then a nutrient requirement for tryptophan is established for the sleep disorder.

## **Evidence Based Medicine and Medical Foods**

The explicit methodologies used to determine "best evidence" were largely established by the McMaster University research group in 1978. The term "evidence based" was first used in 1990, and the term "evidence-based medicine" first appeared in the medical literature in 1992. There are now a large number of Evidenced Based Medical Systems that are designed for various purposes.

An evidence-based rating system is a science-based systematic evaluation of the strength of the evidence behind a statement. In the case of health claims, it would rate the strength

of the evidence behind a proposed substance/disease relationship. A large number of evidence-based rating systems are currently in use today by physicians, dietitians and other health professionals. FDA has tentatively chosen to model its evidence-based rating system on that of the Institute for Clinical Systems Improvement (ICSI) as adapted by the American Dietetic Association with modifications specific to FDA. In making this tentative decision, FDA relied on criteria for evaluating evidence-based rating systems as reviewed and critiqued by the Agency for Healthcare Research and Quality (AHRQ). FDA also found the modifications from the American Dietetic Association to be particularly useful as they considered diet and health relationships, whereas other groups focused on drug and treatment applications.

The FDA has developed a system for evaluating the large body of information that is required to assess the value of therapeutic interventions. (Guidance for Industry, FDA Interim Evidence-Based Ranking System for Scientific Data July 10, 2003 <http://www.cfsan.fda.gov/~dms/hclmgu4.html>) The validation of therapeutic products has been accomplished using this schema advanced by the FDA for assessment of the efficacy of therapies using the concept of Evidence Based Medicine. In the FDA scheme outlined below, the type, quantity, and consistency of evidence is evaluated and graded. The FDA scheme involves several elements:

“Each study would be characterized as a **study design type**. By categorizing the study, it automatically receives an initial study "rating" based on the type of experimental design, which is independent of the quality of the study. The rating of study design is based on the principle of minimizing bias. Only primary reports of data collection are rated. Reports that synthesize or reflect collections of primary reports are not considered part of the rating system although they may provide useful background information”.

1. Study Design Type One  
Randomized, controlled intervention trials
2. Study Design Type Two  
Prospective observational cohort studies
3. Study Design Type Three
  - (a) Nonrandomized intervention trials with concurrent or historical controls
  - (b) Case-control studies
4. Study Design Type Four
  - (a) Cross-sectional studies
  - (b) Analyses of secondary disease endpoints in intervention trials
  - (c) Case series

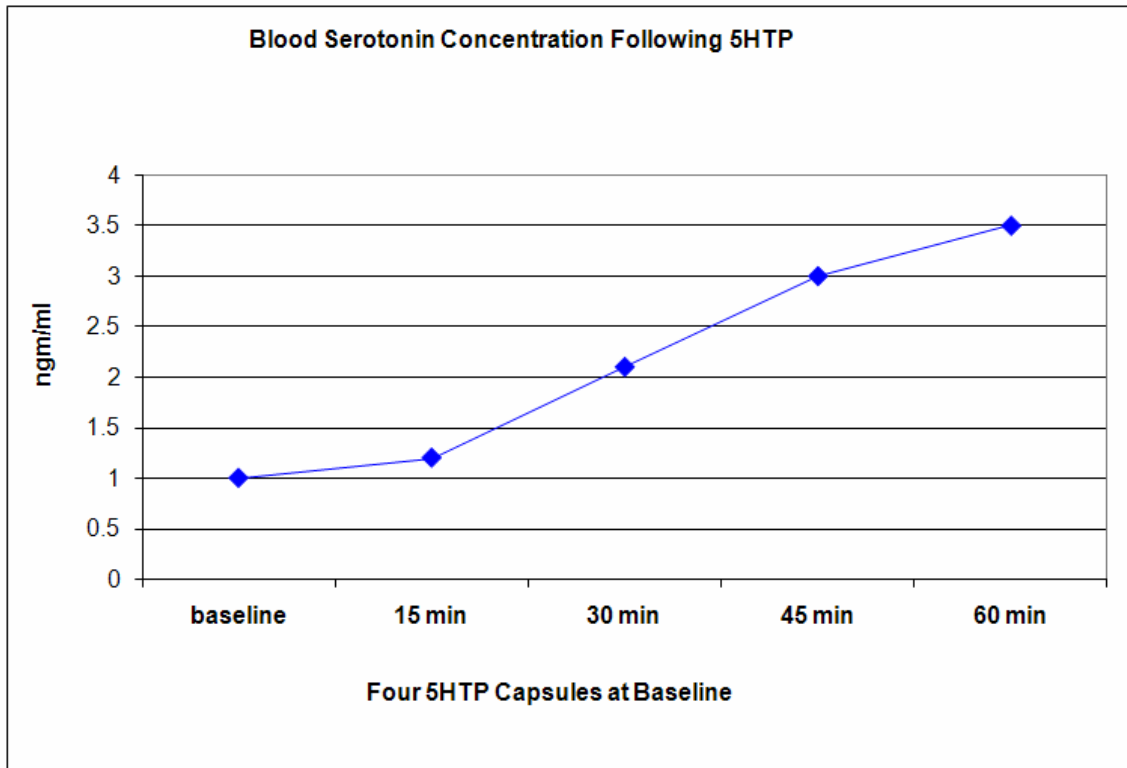
Furthermore, the FDA scheme provides additional criteria including Quantity and Consistency of Data:

- 1) **Quantity.** Considers the number of studies, the total number of individuals studied and the generalizability of the findings to the target population.
  - i) (\*\*\*) means the number of studies and the number of individuals tested (from all studies of design types one and two that are of high quality (+) combined) are sufficiently large to comfortably generalize to the target population.
  - ii) (\*\*) means there are a sufficient number of studies and individuals tested from study design type three and higher (i.e., study design types one and two) of at least moderate quality (Ø) but uncertainties remain as to generalizability to the target population.
  - iii) \*) means that the number of studies and the number of individuals tested is insufficient to generalize to the target population.
  
- 2) **Consistency.** Considers whether studies with both similar and different designs report similar findings.
  - i) (\*\*\*) means a sufficient number of studies of design types one and two that are of high quality (+) have consistent results. Any inconsistencies should be explained satisfactorily.
  - ii) (\*\*) means there is a moderate consistency across all study levels.
  - iii) (\*) means that the results of studies are inconsistent.

Accordingly, the Medical Food GABAdone has been validated using physiologic endpoints. These endpoints include documentation of the nutrient requirements, performance of physiologic endpoint trials using a controlled crossover design, and performance of double-blind placebo-controlled trials using sleep architecture scales with both visual analogue scales and Likert numeric scales.

**Using the FDA scheme for Evidence Based Medicine, GABAdone is rated Type 1, Quantity \*\*\*, Consistency\*\*\* (T1.Q\*\*\*.C\*\*\*). This is the highest quality data.**

There is a large body of peer-reviewed published data supporting the nutritional requirements for tryptophan, choline, and GABA in sleep disorders. The studies are consistent with little controversy concerning the nutrient deficiency of these amino acids in sleep disorders. The majority of FDA approved pharmaceuticals for sleep disorders have as their mechanism alteration of neurotransmitters such as serotonin and GABA.



Administration of tryptophan as 5HTP in our studies increases serotonin blood levels, confirming published data.

### **GABAdone Dosage**

One or two capsules of GABAdone should be taken at bedtime, with an additional dose during the night if the patient awakens and cannot fall back to sleep. As with all Medical Food products, the best dosing protocol is established by the healthcare provider in coordination with the requirements of each individual patient.

### **GABAdone and Prescription Drugs**

In patients taking pharmaceutical agents to induce and maintain sleep, it is suggested that the medication dosage should be reduced gradually. GABAdone should be taken with the pharmaceutical sleep agent at bedtime. If restorative sleep is obtained with the combination, the drug should be slowly tapered off under medical supervision.

### **Side Effects**

The side effect profile of GABAdone is comparable to the rate of food intolerance in the community. The ingredients of GABAdone are derived from nutrient based compounds found in the normal food chain. Food intolerance is an adverse reaction to food that does not involve the body's immune system.

When first starting any amino acid therapy, some people complain of mild headaches, stomach upset, or mouth dryness. These symptoms are transient, mild, and temporary and can be managed by drinking plenty of fluids and carefully titrating the dose. These side effects are relieved by lowering the dose initially and slowly increasing until reaching the recommended dosing level.

### **Background:**

GABAdone contains a formula blend of selected GRAS (generally recognized as safe) ingredients that are found in the normal human food chain. The primary ingredients are key amino acids, the building blocks of protein. The GABAdone formula is designed to induce increased neurotransmitter function in patients with sleep disorders, and to increase the function of the neurotransmitters serotonin, acetylcholine, and GABA. The GABAdone formula is based on a five-component patent pending process. This process provides for a five-component system to allow for the conversion of a neurotransmitter precursor into a neurotransmitter. The five-component system includes: (1) each neurotransmitter is synthesized from an amino acid precursor, (2) stimulation of the uptake of the neurotransmitter precursor is required to initiate the conversion of a precursor to a neurotransmitter, (3) since most neurons are inhibited from firing, an adenosine antagonist such as and cocoa powder is added to disinhibit the neuron, (4) stimulation of neurons to release a specific neurotransmitter is required, and (5) a system must be used to prevent attenuation of the precursor response, a well known precursor phenomena. GABAdone has been formulated to encompass this five-component system and targets the neurotransmitters acetylcholine, serotonin, and GABA.

GABAdone is designed to produce three neurotransmitters including acetylcholine, serotonin, and GABA. Requirements for these three neurotransmitters are involved in the development of certain sleep disorders<sup>(1-62)</sup> <sup>(51;63-104)</sup> <sup>(105-117)</sup>. If the timing and secretion of these three neurotransmitters is altered, normal sleep cycles and restorative sleep do not occur. For example, the benzodiazepine drugs reduce sleep latency, but abolish phase IV- V sleep and REM sleep.

GABAdone is designed to produce neurotransmitters related to physiologic functions including initiation of sleep, maintenance of sleep, and re-induction of sleep upon awakening during the night. In the GABAdone formulation, choline is used as a precursor to acetylcholine, and 5-hydroxytryptophan is used to induce the physiologic production of serotonin<sup>(118)</sup>.

Thus, the GABAdone formula contains the neurotransmitter precursor 5-hydroxytryptophan as a precursor to serotonin; choline as a precursor to acetylcholine; GABA is directly administered as an inhibitory neurotransmitter.

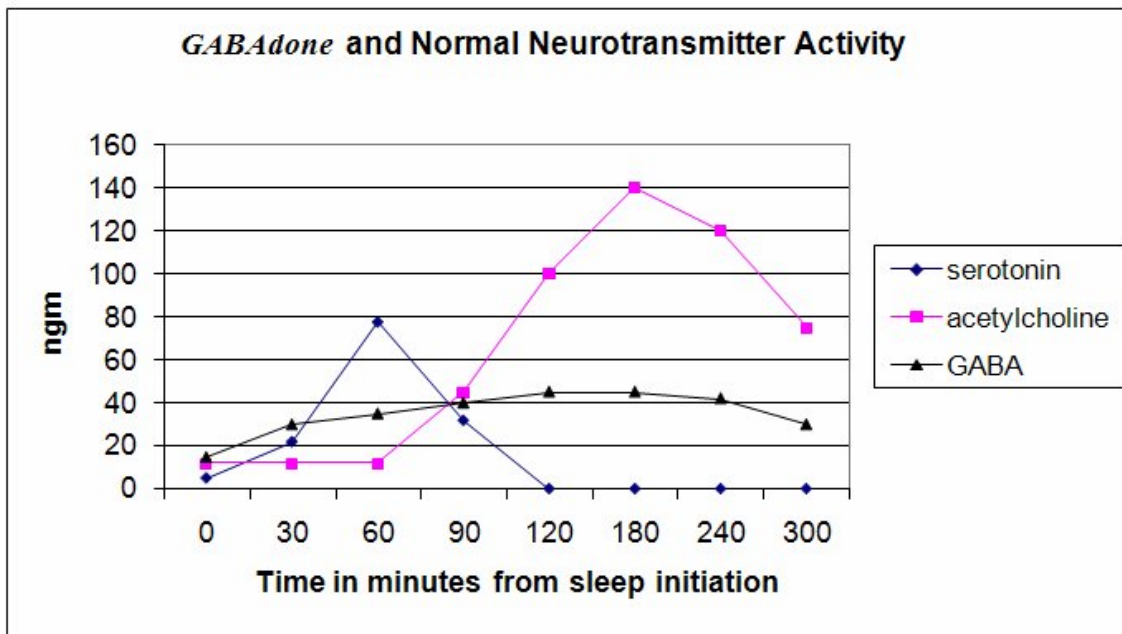
In the GABAdone formula, Ginkgo Biloba is used as an uptake stimulator<sup>(119-124)</sup>. Glutamic acid is used to produce glutamate, a neuronal stimulator<sup>(125-156)</sup>. Cocoa is used to disinhibit the adenosine brake <sup>(157-167)</sup> <sup>(168-171)</sup>. Grape seed extract, containing polyphenols<sup>(172-175)</sup>, is used to avoid the attenuation usually associated with neurotransmitter precursor administration. GABA is administered as an inhibitory neurotransmitter<sup>(176-186)</sup>.

Release of serotonin initiates sleep and reduces sleep latency (<sup>10;13;20;27;38;46;75;78;82;187-222</sup>) (<sup>51;55;94;223-241</sup>). The timing of serotonin release is critical for the initiation of sleep, and the amount of serotonin released is also critical for the initiation of sleep. At the initiation of sleep, a small amount of serotonin is released. The amount of serotonin peaks within several hours after sleep initiation. Failure to produce the necessary amount of serotonin will result in failure to initiate sleep. Insufficient serotonin production and conversely, excessive serotonin interfere with the initiation of normal sleep.

Serotonin is intimately involved in sleep apnea, snoring, REM sleep, and depression associated with sleep disorders (<sup>20;84;197;242-288</sup>) (<sup>244;244;285;285;289-297;297;298;298;299;299-302;302-306;306-311;311-330</sup>) (<sup>331-350</sup>). An alteration of the tryptophan/serotonin axis will result in altered sleep patterns. Appropriate and timely production of serotonin will ameliorate sleep disorders.

Production of acetylcholine after initiation of sleep results in restorative, Delta IV-V sleep (<sup>51; 78; 88; 94; 103; 351-393</sup>). Following the burst of serotonin that initiates sleep, acetylcholine release increases the duration of phase IV and V sleep. In addition, the release of acetylcholine increases the frequency of REM sleep episodes and the duration of these episodes. The commonly used hypnotic drugs abolish phase IV and V sleep and inhibit REM sleep.

GABA is the main inhibitory neurotransmitter. The initiation and maintenance of sleep depends on the availability of GABA to the GABA-receptors (<sup>51;51;375;375;394-396;396;397;397-399;399;400;400-407;407-409;409-419</sup>). The most commonly used hypnotic drugs act by sensitizing the GABA receptors to GABA (<sup>420-432</sup>). GABA creates general inhibition of the nervous system to allow normal sleep.



The carefully timed activation of the three neurotransmitters--serotonin, acetylcholine, and GABA—is required to initiate sleep, maintain sleep, and increase the REM sleep time.



Accordingly, the GABAdone formula contains a proprietary blend of precise amounts of 5-hydroxytryptophan, GABA, cocoa powder, grape seed extract, glutamic acid, and choline.

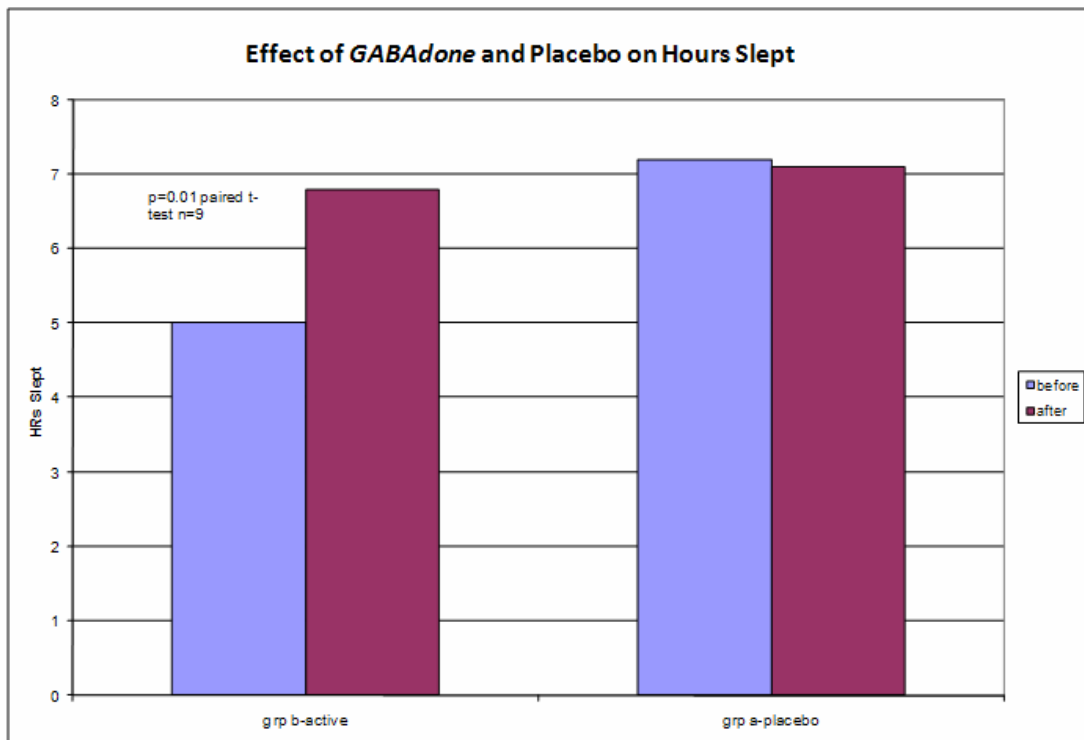
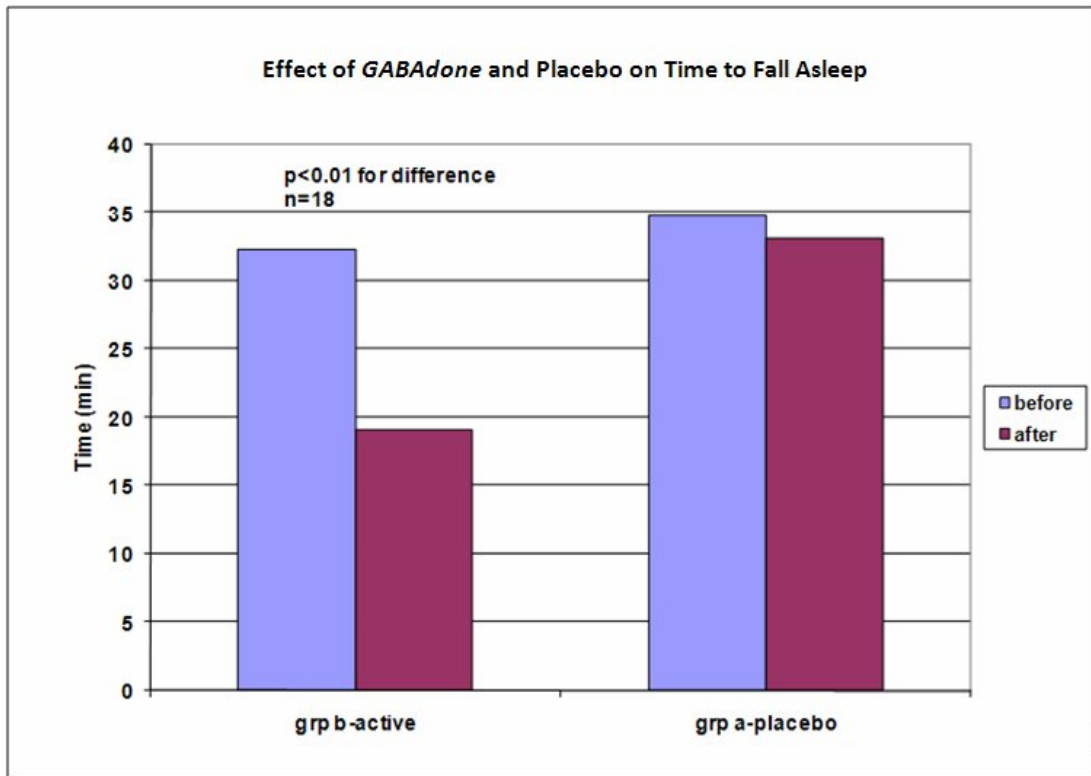
The GABAdone formula is designed to provide precursors for the neurotransmitters that induce and maintain restorative sleep. These amino acid precursors are 5-hydroxytryptophan, choline, and GABA. In addition, GABAdone depends on activation of amino acid utilization by glutamate, and the theobromine in cocoa. Several open label trials have been performed using the combination of 5-hydroxytryptophan, choline, GABA, and cocoa. These trials have shown induction of sleep, maintenance of sleep, reduced snoring and restorative sleep.

### **Nutritional Requirements Associated with Sleep Disorders**

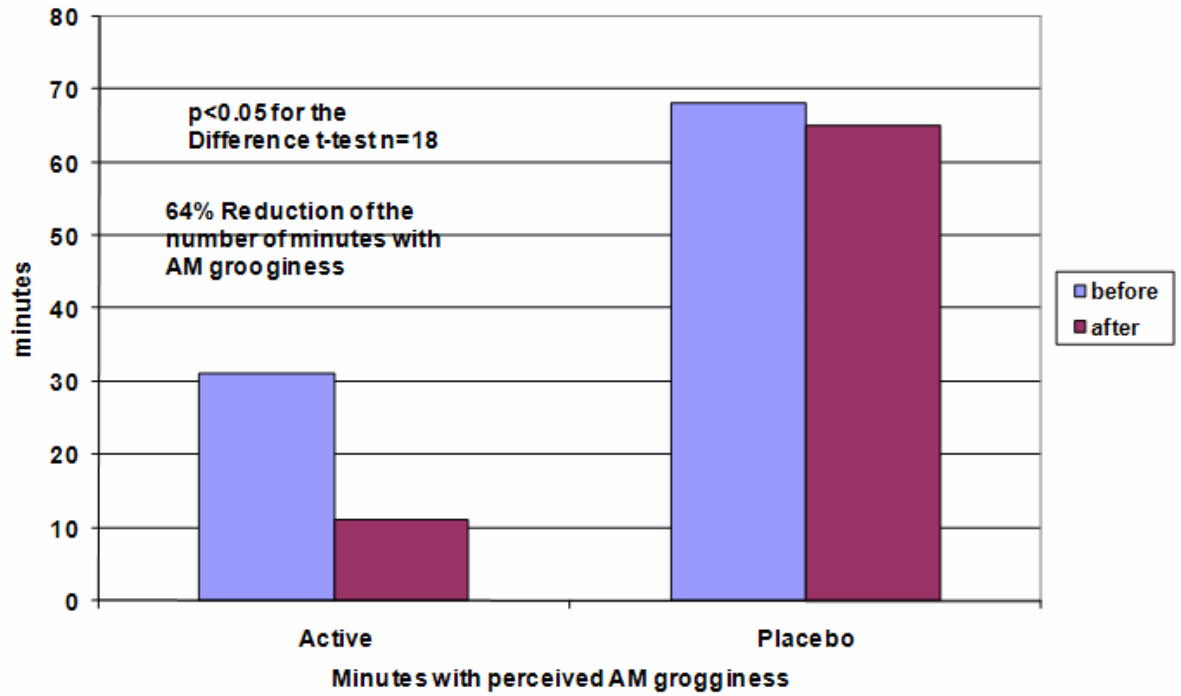
Patients with sleep disorders have been found to experience nutritional deficiencies of tryptophan, choline, and GABA. Patients with sleep disorders frequently exhibit reduced blood levels of serotonin<sup>(58;433-462)</sup> and 5-hydroxytryptophan. Moreover, obese patients use more tryptophan than lean patients. Reduced calorie diets that are frequently reduced protein diets, result in a further fall in blood tryptophan that tend to exacerbate sleep disorders. Patients with sleep disorders often exhibit a deficiency of tryptophan<sup>(463-489)</sup> as measured by reduced blood levels as well as an alteration of tryptophan metabolism.<sup>(490;491;491-497;497-506;506-508;508;509;509-513;513-528;528;529;529-535;535-578)</sup> <sup>(579;580;580-586;586-591;591-598;598-606;606-610;610-638)</sup>.

Choline deficiency has been associated with certain sleep disorders<sup>(88;91;94;212;228;356;399;639-655)</sup> <sup>(656-659)</sup>, particularly those associated with sleep apnea syndromes<sup>(31;31;660;660-665;665-677;677-692;692-695;695;696;696-698;698-734)</sup>. Other sleep disorders have been associated with requirements for serotonin and acetylcholine precursors, and can also be associated with insensitivity to circulating GABA.

In a double-blind placebo-controlled trial of *GABA*done several measures of sleep architecture showed statistically significant improvement as illustrated by the three graphs below.



### Effect of *GABA*done and Placebo on AM Grogginess



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