



***AppTrim*[™] Product Information**

Appetite Suppressant for Obesity Management

Medical Foods Classification

AppTrim is a Medical Food formulated by practicing physicians to meet the nutritional requirements of obese patients and to be used for specific dietary management of obesity. ***AppTrim*** provides the amino acids that are precursors to the neurotransmitters that control appetite. In addition, ***AppTrim*** provides the amino acids that are known to suppress Neuropeptide Y, the hormone that controls hunger. Under the regulations of the Food and Drug Administration, Medical Foods may only be used when a patient is under the ongoing care of a physician or other healthcare provider. Medical Foods are used for the dietary management of disease states with known nutritional requirements. Medical Foods must contain ingredients from the human diet and cannot be sold directly to patients or used without medical supervision.

Distinctive Nutritional Requirements

Obesity is associated with inability to control appetite, satiety, and carbohydrate cravings. Appetite, feelings of satiety, and carbohydrate cravings are under the control of specific neurotransmitters, including norepinephrine, serotonin, and Neuropeptide Y. Serotonin and tryptophan deficiencies have been documented in obese patients. Brain histamine causes the release of the neurotransmitter CRH. Release of brain CRH causes suppression of Neuropeptide Y, the hunger molecule. Therefore a deficiency of histidine, the precursor to histamine, will result in inadequate suppression of Neuropeptide Y. Choline is required by presynaptic ganglion to produce adequate quantities of epinephrine and norepinephrine. In addition, tyrosine deficiencies have been reported in the medical literature in obese patients. Thus, obesity is associated with the distinct nutritional deficiency of inadequate tyrosine, tryptophan, L-histidine, and Choline. Obese patients consume increased calories because they lack adequate quantities of these key amino acids.

Indications for Use

1. Obesity
2. Morbid Obesity

Neurotransmitter Production in the Human Body

1. Tyrosine produces norepinephrine
2. Tyrosine produces epinephrine
3. Choline produces Acetylcholine
4. 5-hydroxytryptophan produces Serotonin
5. Histidine produces Histamine

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 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, **AppTrim** maintains its effectiveness and does not attenuate.

AppTrim Ingredients

Tyrosine, Choline Bitartrate, 5-Hydroxytryptophan, Hydrolyzed Whey Protein, Histidine, Serine, Glutamic Acid, Grape Seed Extract, Caffeine, and Cocoa. Supplied as 120 capsules per bottle. 12 bottles per case. A serving of **AppTrim** contains a small amount of caffeine, approximately equal to the amount of caffeine found in half a cup, of coffee- (6 oz or 8 oz) one cup = 120 mg.

AppTrim is also available without caffeine. **AppTrim-D** contains the same ingredients as the original formula, only caffeine has been eliminated.

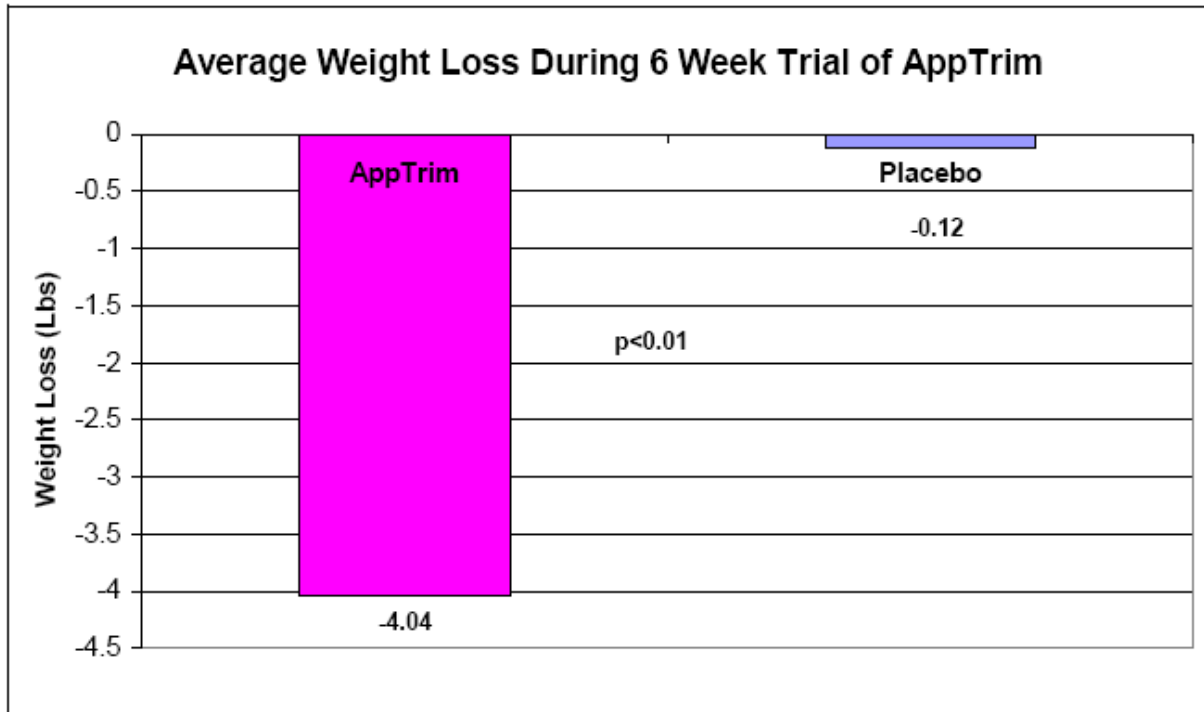
Targeted Cellular Technology and **AppTrim**

AppTrim is designed to produce the neurotransmitters norepinephrine, epinephrine, serotonin, acetylcholine, brain histamine, and glutamate. Glutamate serves as the neuronal stimulator, norepinephrine reduces appetite, serotonin reduces carbohydrate craving, and epinephrine induces fat burning. Brain histamine suppresses Neuropeptide Y, the hunger hormone. Decreased brain serotonin levels are associated with obesity due to overeating. A relative deficiency of serotonin is believed to be associated with the brain's perception of starvation and hunger. Tryptophan is one of the most rare of the essential amino acids-one that the body cannot produce, but one that is needed for the production of vital proteins. Consequently, the dietary depletion of tryptophan, a serotonin precursor, is an ideal homeostatic mechanism in the brain for regulating the desire for food intake.

AppTrim and Clinical Trials

There have been nine double blind clinical trials during the development of the **AppTrim** formula. When **AppTrim** was given as an adjunct to a weight loss diet, an average of 4.2 pounds weight loss was shown over a six-week period. Weight loss of as much as 15 pounds per month has been observed in certain patients in clinical practice. A weight loss of 1 to 2 pounds per week is recommended in order to sustain weight loss. Weight loss of more than 2 pounds per week can be obtained with **AppTrim** but close medical supervision is advised if more than 2 pounds per week of weight loss is the goal. While weight loss is the quantitative measurement for the efficacy of **AppTrim**, this is not a

weight loss product per se and is not a dietary supplement. Rather, as a Medical Food, **AppTrim** meets the distinctive nutritional requirements for the management of obesity.



AppTrim Dosage

AppTrim is intended to be given in a two-capsule dose twice daily at mid morning and mid afternoon. Some patients appear to respond well to a one-capsule dose, while others have found a three-capsule morning dose, and a one-capsule afternoon dose to be effective. 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. There is no unsafe upper limit of dosage of **AppTrim** as any excess amino acid will be deaminated in the liver.

AppTrim and Diet

AppTrim has been tested with a variety of diets including the Atkins' Diet, the Zone Diet, and the South Beach Diet. Dietary management of obesity can be obtained with any of these diets using **AppTrim** for appetite suppression. It is recommended that **AppTrim** be used to produce appetite suppression with a reduced calorie, balanced diet. Patients should be advised to eat breakfast, lunch, and dinner, with an emphasis on reduced portion sizes and elimination of refined carbohydrates. Weight loss is consistently achieved with a 1200-calorie diet for women and a 1600-calorie diet for men. Foods with a high glycemic index should be eliminated from the diet. When target weight is achieved, the dose of **AppTrim** can be adjusted on an individual basis to help maintain appetite suppression over the long term.

Side Effects

The side effect profile of **AppTrim** is comparable to the rate of food intolerance in the community. The ingredients of **AppTrim** 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 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:

Current methods of obesity management are inadequate despite the large number of clinical trials of pharmaceuticals agents, dietary supplements, and mechanical interventions that have been performed.^{1-16,17-33,34-49,50-67,68-84,85-106,107-132,133-158,159-192,193-214,215-223,224-255,256-276} It is well established that traditional obesity management programs are minimally effective in producing either short-term or long lasting weight reduction results. Moreover, many of the proposed treatments, particularly the pharmaceutical agents, exhibit significant side effects, including death and serious heart valve disease. Accordingly, there is a need for a safe and effective obesity management method that is based on naturally occurring food components to aid in achieving and maintaining optimal weight.

AppTrim contains a specially formulated 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 **AppTrim** formula is designed to induce increased neurotransmitter function leading to appetite suppression and weight control. The **AppTrim** formula is designed to increase the function of the neurotransmitters serotonin, epinephrine, norepinephrine, and histamine, which are lacking or diminished in obese patients. The **AppTrim** formula is based on a five-component, patent pending process. This process allows 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 caffeine and cocoa powder is added to disinhibit the neuron, (4) stimulation of neurons to release a specific neurotransmitter is required; and (5) a mechanism must be used to prevent attenuation of the precursor response, a well known precursor phenomena. **AppTrim** has been formulated to use this five-component system to target the neurotransmitters norepinephrine, epinephrine, acetylcholine, histamine, and serotonin to effectively suppress appetite and carbohydrate craving.

AppTrim is designed to produce four neurotransmitters including norepinephrine/epinephrine, acetylcholine, histamine, and serotonin. The four neurotransmitters are involved in appetite control²⁷⁷⁻³⁰⁴, ³⁰⁵⁻³⁵⁰, early satiety²⁹³, ³⁵¹⁻³⁵⁷,

carbohydrate craving control³⁵⁸⁻³⁶⁴, release of CRF³⁶⁵⁻³⁶⁸, inhibition of NPY^{367, 369-373}, preferential fat utilization^{374 375} and thermogenesis³⁷⁶⁻³⁹⁶. Appetite control is the reduction of the feelings of hunger during a period of food deprivation. Early satiety is the feeling of fullness or satiation with the ingestion of small amounts of food. Carbohydrate craving is the desire to ingest sugar and other forms of carbohydrates. Release of the hypothalamic hormone CRF reduces appetite while release of the hypothalamic hormone Neuropeptide Y causes increased hunger along with increased intake of calories. Preferential fat burning is the use of calories from fat rather than carbohydrate and protein during a period of weight loss resulting in reduced percent body fat. Thermogenesis is the increase in metabolic rate and the burning of excess calories.

AppTrim is designed to produce neurotransmitters related to physiologic functions including appetite control, carbohydrate craving control, thermogenesis, and preferential fat utilization. In the **AppTrim** formula, tyrosine is used as a precursor to norepinephrine/epinephrine³⁹⁷. These two neurotransmitters are thermogenic³⁹⁸⁻⁴⁰⁶ and liberate free fatty acids^{407 408-410} to induce preferential fat utilization. Norepinephrine is an appetite suppressant^{282, 411-435 312, 436-456 341, 457-486} and induces early satiety^{487, 488}. 5-hydroxytryptophan is used to induce the physiologic production of serotonin³⁹⁷; serotonin production reduces carbohydrate craving^{308, 314, 316, 334, 347, 359, 362, 363, 489-524}. Acetylcholine is the neurotransmitter in the pre-synaptic ganglion of the sympathetic nervous system³⁹⁷. The sympathetic nervous system produces epinephrine and norepinephrine. The choline in the **AppTrim** formula is used to induce the physiologic production of acetylcholine in order to produce physiologic amounts of norepinephrine and epinephrine, thus inducing thermogenesis, appetite suppression, and early satiety. Histidine is the precursor to histamine³⁹⁷. Brain histamine will increase the production of CRF and inhibit production of Neuropeptide Y^{333, 481, 525-538}.

The **AppTrim** formula contains the neurotransmitter precursor tyrosine that produces norepinephrine/epinephrine; 5-hydroxytryptophan and hydrolyzed whey protein as precursors that produce serotonin; choline as a precursor that produces acetylcholine; histidine as a precursor that produces histamine.

In the **AppTrim** formula, serine is used as an uptake stimulator⁵³⁹⁻⁵⁴². Glutamic acid is used to produce glutamate, a neuronal stimulator⁵⁴³⁻⁵⁷⁴. Caffeine and cocoa are used to disinhibit the adenosine brake^{575-585 586-589}. Grape seed extract, containing polyphenols⁵⁹⁰⁻⁵⁹³, is used to avoid the attenuation usually associated with neurotransmitter precursor administration.

Accordingly, the **AppTrim** formula contains precise, proprietary amounts of hydrolyzed whey protein (containing 5-hydroxytryptophan), caffeine, Griffonia seed extract, cocoa powder, L-histidine, L-serine, L-tyrosine, grape seed extract, glutamic acid, and choline.

The **AppTrim** formula is designed to provide precursors for known neurotransmitters that influence appetite, early satiety, craving for carbohydrates, and thermogenesis. The amino acid precursors are tyrosine, tryptophan (within the hydrolyzed whey protein), 5-hydroxytryptophan, choline, and histidine. In addition, **AppTrim** depends on activation of amino acid utilization by glutamate, caffeine, and the theobromine in cocoa. Nine double blind placebo controlled trials have been performed using the combination of tyrosine, histidine, choline, and cocoa. These trials have shown weight reduction and

reduction of percent body fat as measured by both electrical impedance and x-ray densitometry. One of the nine studies has been published. (*JANA, Vol.1, No. 2, Fall 98*)

AppTrim contains both caffeine and cocoa but no ephedra or ephedrine alkaloids. Caffeine has actions similar to those of theobromine in cocoa. Both agents function by inhibition of the neuronal adenosine brake. The concentration of caffeine in a single dose is similar to that in an 8-ounce cup of coffee.

Nutritional Requirements Associated with Obesity

Many obese patients have nutritional requirements despite their large body mass. They have stored energy in the form of fat and have lost the ability to control appetite through amino acid based messengers—they are relatively protein starved. For example, tryptophan is a precursor to serotonin^{288, 594, 595}. Serotonin controls craving for carbohydrate⁵⁹⁶. Obese patients often have reduced blood levels of serotonin^{312, 314, 494, 597-624}. Moreover, obese patients use more tryptophan than do lean patients. Finally, reduced calorie diets that are often reduced protein diets, result in a further fall in blood tryptophan, and exacerbate carbohydrate craving. Thus, obese patients despite their body mass, frequently show a deficiency of tryptophan^{347-350, 360, 363, 504, 511, 512, 518-520, 524, 625-638}.

Release of Neuropeptide Y (NPY) causes increased hunger⁶³⁹⁻⁶⁴⁴. Hunger is maintained until sufficient protein is ingested to suppress NPY. At approximately mid-morning, when the stomach is empty, the gut releases the peptide Ghrelin that stimulates the release of NPY from the hypothalamus⁶⁴⁵⁻⁶⁵⁰. This further stimulates hunger and initiates feeding. Three hormones are released during feeding that suppress NPY and create satiety. These hormones are PYY⁶⁵¹⁻⁶⁵³, MSH^{654, 655} and CRF⁶⁵⁶⁻⁶⁵⁸. The hormone MSH is released by the brain in response to increased blood levels of tyrosine⁶⁵⁹⁻⁶⁶³. The hormone CRF is released by the brain in response to increased blood levels of histidine⁶⁶⁴⁻⁶⁷⁴. In a low protein low calorie diet, there is insufficient tyrosine or histidine ingested so that satiety does not occur and hunger rapidly returns after eating. There is a relative deficiency of tyrosine and histidine associated with obesity and dieting.

Finally, the interplay of the hunger producing and hunger suppressing hormones depends on the availability of insulin and the degree of insulin resistance⁶⁷⁵. When there is either no insulin or the body is insulin resistant, the body requires increased concentration of tryptophan, tyrosine, and histidine to inhibit hunger and create early satiety. In insulin resistant patients, even normal amounts of tyrosine and tryptophan ingestion are inadequate to produce satiety and prevent hunger.

Obesity and weight gain are associated with a series of absolute and relative nutritional deficiencies of important amino acids that control appetite, carbohydrate craving, and satiety.

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