## patent highlights

## SOMALIFE HEALTH PRODUCTS INC.

Patent No. - US 6,346,264 B1 • Date of Patent - February 12, 2002



- The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.
- ...the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States...
- A nutritional supplement for ingestion by humans for restoring growth hormone levels...
- This invention relates to the field of nutritional supplements, including supplements which elevate release of human growth hormone.
- Until recently human growth hormone (hereinafter alternatively referred to as HGH) was available only in expensive injectable forms and benefits from the restoration of HGH levels available only to those with the ability to pay. Most recently natural substances which can trigger the release of human growth hormone from an individual's own anterior pituitary gland have become available. These are generically referred to as secretagogues.
- In 1981 a study was published by Drs. Isidori, Lo Monaco and Cappa.
- If offered a more practical and physiological approach to the previously known fact that intravenous administration of amino acids strongly stimulates the secretion of human growth hormone....
- ...the age-related changes in body composition should be correctable in part by the administration of human growth hormone, now readily available as a bio-synthetic product.
- The primary purpose of HGH is that of stimulating growth, cell repair and regeneration. Once the growth period is over, its primary function becomes that of cell regeneration and repair, helping to regenerate skin,

- bones, heart, lungs, liver and kidneys to their former youthful cell levels. Elevating HGH levels appears to benefit the immune system. It has also been reported the risk factors for heart attack and stroke may be potentially diminished. Some patients with emphysema have reported that they are less short of breath. Dr. Rudman's study also demonstrated that bone density in the lumbar spine can improve. It has also been shown that wrinkled skin diminishes. Others have reported improvement in presbyopia (the difficulty in focusing due to hardening of the lenses as we age) with some reporting restoration of hair colour and growth. HGH appears to selectively reduce the fat around the abdomen, hips, waist and thighs while at the same time increasing muscle mass.
- It appears that HGH not only has the ability to restore sexual potency and sexuality in older men, but acts as a mood elevator, restoring a youthful sense of wellness as well as improving sleep. With its potential for affecting cell regeneration and repair, healing of injuries should improve.
- ...HGH levels decline with age. Therapeutically, many of these hormones can be replaced to offset some of the effects of aging such as menopausal symptoms in women or erectile dysfunction in men.
- Daily growth hormone secretion diminishes with age with roughly half the levels at age forty that we had when we were twenty, and about one-third of those youthful levels at age sixty. In some sixty-year olds the levels are as low as 25% of the HGH levels in a twenty-year old.
- Low HGH levels are associated with the aging process and early onset of disease. For example, Rosen and Bengtsson noted an increased death rate from cardiovascular disease in HGH deficient patients...
- HGH, once released by the pituitary gland, travels in the circulation and is taken up principally by the liver where it stimulates the production of IGF-1. IGF-1 is then released

into the circulation where it attaches to cells in the body and like insulin, triggers the cell to produce certain responses which, with IGF-1, are those of growth, regeneration and repair. Levels of IGF-1 are monitored by the hypothalamus situated just above the pituitary gland. When maximal HGH levels are attained for any individual, these levels trigger the release of Somatostatin. This feedback loop prevents excessive levels of HGH in the body. This feedback loop is extremely efficient at monitoring and maintaining the HGH (and therefore IGF-1) at the optimal level for the individual.

- The present invention is a nutritional supplement. It is an amino acid stack secretagogue, which, taken orally, stimulates the pituitary gland to produce
  HGH/Somatotropin. One object of the present invention is to elevate HGH/Somatotropin release. This has the further result of increasing IGF-1 levels. Further objects of the present invention may also result, namely, inhibiting insulin depression; inhibiting hyperglycaemia and increasing insulin effectiveness; enhancing fat conversion, assisting in lowering cholesterol, and normalizing lipid balance.
- As noted above, elevating HGH levels elevates IGF-1
  levels. This can be achieved by secretagogue HGH releasers
  without the need for injection therapy or oral-HGH forms,
  or gene manipulation. Secretagogues maintain the body's
  own natural feedback loop, thus not only releasing HGH
  naturally but safely. Natural secretagogues may have the
  ability to more closely mimic the body's youthful HGH
  secretion patterns than any other HGH therapies currently
  available.
- The supplement of the present invention contains amino acids, formulated as a dietary supplement.
- Arginine along with Lysine have been demonstrated to cause HGH release when combined in specific proportions.
   Essential amino acids contained in the supplement of the present invention are Isoleucine, Leucine, Lysine and Valine. Lysine boosts the effectiveness of Arginine and is also said to affect growth as well as having immuneboosting properties of its own.
- The supplement of the present invention works as a dietary supplement by assisting the body's own ability to secrete HGH naturally in a manner which is safe and effective as well as being affordable.
- The supplement of the present invention may be formulated in a capsule form for ease of ingestion. It

- should be taken on an empty stomach. This ensures that it is rapidly absorbed into the bloodstream.
- The supplement of the present invention in the specified combination and having the specified quantity of glutamine inhibits hyperglycaemia, while ensuring a natural anabolic muscle building effect by increasing insulin effectiveness. In the supplement of the present invention ornithine is combined with glutamine to enhance fat conversion and assist in lowering cholesterol, while normalizing lipid balance.
- ...stacked amino acid secretagogues resulting in balancing glucose, insulin and blood lipids.
- ...so as to provide essential nutrients for muscle regeneration and repair. This is of particular importance when a secretagogue is used before exercise.
- The combination of types of amino acids, mass ranges and specific formulations have been selected to be synergistically balanced and of adequate quantity to achieve the desired physiological effect, namely, growth hormone release. Improper combinations of the amino acids or insufficient quantities of amino acid salts will be ineffective. The component amino acids are synergistic in the sense that several of them when combined together, arginine, lysine, glutamine, ornithine and glycine, synergistically stimulate the release of human growth hormone. The combination was also chosen to inhibit chemical combination or reaction between the amino acids. Such will not occur because of the crystalline freeform amino acid salts that have been chosen.
- A further novel aspect of the supplement of the present invention is the addition of the sulphur-containing branch-chain amino acids leucine, iso-leucine and valine, all of which themselves have a synergistic effect in combination with the human growth hormone that is released in helping to build and improve muscles mass and strength.
- A nutritional supplement for ingestion by humans for restoring growth hormone levels consisting of unmodified rapidly absorbed free-form crystalline amino acids, in an amino acid stack which does not include non-amino acid nutritional supplementation, and which, when digested by a user, stimulates release of human growth hormone in the user, wherein said amino acids consist of the amino acids leucine, isoleucine, valine, lysine, glutamine, ornithine and glycine.