

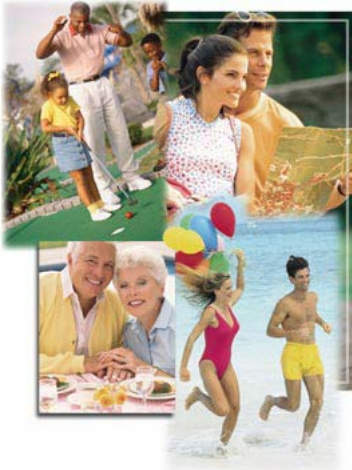
REGENESIS

THE ORIGINATORS OF ORAL SPRAY GROWTH HORMONE

Thank you for your interest in Regenesi s GH, the world's finest oral spray growth hormone from the originator in oral spray Growth Hormone technology. The fact is today, one person in the United States will turn 55 years of age every 7.7 seconds. Some of these 77 million baby boomers may be your family members, your friends, your patients or maybe . . . even you. **Along with the aging of our society there comes a seemingly endless list of age related diseases. People certainly don't want to experience the effects of aging. The question is . . . do they have to?**

Growth Hormone is abundant in the body when people are young. During that same time they have seemingly endless energy, creativity and an attitude that they can accomplish nearly anything. As we grow older our bodies produce and release less Growth Hormone each year - our bodies also begin to deteriorate in many ways . . . and what happens to those marvelous youthful attributes we once had?

MORE BALANCED, YOUTHFUL HORMONES



Clinical evidence demonstrates that by increasing Growth Hormone levels we can dramatically reverse many negative health symptoms that develop with aging.

The drawbacks to injected GH are that it is inconvenient, very expensive and uses unnaturally large doses leading to unwanted side effects. **Injected and oral spray GH work in entirely different manners.** Today we have the effective and affordable alternative from the leader in orally ingested GH. Regenesi s GH is made from authentic, pharmaceutical grade recombinant growth hormone. **Finally there is an effective choice at a price virtually everyone can afford.**

After a double blind clinical study on Regenesi s oral spray GH, Dr. Steven Novil concluded: "There is a significant physiological change with the patients. The direction in movement of hormone levels being brought back to youthful and regenerative levels is significant in of itself." He went on to state, "Supporting data of the double blind study, show that the patients consistently evidenced marked progressiveness towards balance. **The GH spray returned the body to a higher metabolism with greater efficiency and a more youthful level of chemistry ."**

F. Pearl McBroom, MD, Preventive Medicine Specialist, has extensive clinical experience with Regenesi s oral spray GH. **She has documented improvement in greater than 95% of patients studied, including increased energy, improved mental clarity, restoration of hormone balance and an increased sense of well being. In essence, turning back the biological clock .**

Feel Like a Kid Again!

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OVERVIEW

Why should you recommend GH therapy to your patients?

The benefits of increasing GH levels in adults (30 yrs+) have been well documented. Slowing, stopping or even reversing the biological aging process is simple, practical and possible. Revitalization of energy levels, increased immune functions, regeneration of all major organs (including the skin) and strengthening of bones are just a few of the benefits of increased GH levels *(pages 5-7)*.

Why Regenesi s?

Regenesi s originated oral spray GH. With more experience than anyone else, Regenesi s has learned how to make the most effective and lasting GH spray. We are the only manufacturer with double blind clinical studies and shelf life studies.

Regenesi s GH mimics the body with Low Dosage/High Frequency (LD/HF) therapy. This approach works with the body in the natural GH release cycle *(pages 8-9)*.

Regenesi s GH has shown to lower free serum IGF-1 levels by promoting an increased number of IGF receptor sites *(pages 9-10)*. High levels of free serum IGF (and insulin) have been associated with obesity, diabetes and many cancers.

Patients who have been on Regenesi s GH tell us the benefits continue over the years they have taken the product. They become more youthful both physically and mentally. And because of that, they return for product month after month.

Why you should recommend Regenesi s GH to your patients? Because it works!

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WHAT IS GROWTH HORMONE?

Human Growth Hormone (GH, HGH, or Growth Hormone) commonly called somatotrophin (somatotropin) or somatotrophic hormone, is a polypeptide hormone with a molecular weight of 21,000 (composed of 191 amino acids), and is produced by the pituitary gland, a small gland located deep inside the brain, directly behind the eyes. It influences the growth of cells, bones, muscles and organs throughout the body. GH is one of many endocrine hormones, like estrogen, progesterone, testosterone, melatonin and DHEA, that all decline in production with age.

HGH affects many body tissues. In adolescents it stimulates linear growth and the aging of the bones. In addition, HGH stimulates the intracellular transport of amino acids and causes nitrogen retention, a supposed marker of protein anabolism. The activity of messenger RNA is also affected, causing increased protein synthesis in specific cells. In addition, HGH stimulates the intracellular breakdown of body fat so that more fat is used for energy. The synthesis of collagen (the sticky substance that is the glue of the body) is stimulated, which is necessary for strengthening of cartilage, bones, tendons, and ligaments. Finally, HGH stimulates the liver to produce somatomedins, which are messenger molecules sometimes referred to as growth factors. To put it simply, there is no other substance known to man that has such far reaching ability to prevent and reverse the conditions of aging.

GROWTH HORMONE SECRETION

- ♦ The rate of GH secretions can rise or fall within minutes, with the highest levels occurring after strenuous exercise and during deep sleep.
- ♦ Most other changes are usually related to the concentration of nutrients in the blood (protein, fat and sugar).
- ♦ The release of GH is also affected by stress, excitement and trauma.

"I find it sad that people are aging, have a lesser quality of life, and die prematurely when they could be on hormonal treatment. This is the medicine of the future."

Dr. Thierry Hertoghe, M.D

SUBLINGUAL GROWTH HORMONE

Growth Hormone has been called the Holy Grail of the anti-aging movement. GH is a master hormone, affecting almost all body tissues and controlling many functions, as well as acting on the mind. No other hormone is more fundamental to our ability to turn back the clock on the effects of aging. No other hormone has been as difficult to make available to the public in a safe, effective oral product. But now it's been done, and you can offer your patients a truly effective, nonprescription Growth Hormone product.

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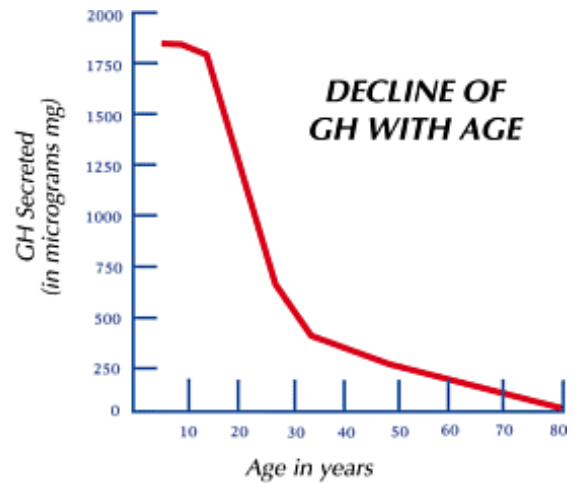
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For over a decade, people throughout the world have been achieving dramatic anti-aging results with prescription GH at very high prices. Until just a few years ago, oral absorption of GH, composed of 191 amino acids, had been ineffective. That of course has all changed. Scientists have succeeded in embedding this GH molecule in a polymer matrix, creating orally absorbable Growth Hormone.

What we are speaking about is not a precursor, a secretagogue, or simply a GH releaser. Regensis GH is true rhGH, as determined by lab analysis by Quest Diagnostic laboratories of the prestigious Corning-Nichols Institute (*page 28*).

WHAT HAPPENS TO GH AS WE AGE?

The secretion of GH peaks by the early 20's when structural growth diminishes. Production of GH then falls more than 75% from age 20 to 60. As you will see from the graph *[right]*, practically everyone over the age of 40 has a GH deficiency. Somatopause, the decline of Growth Hormone, sometimes refers to the physical conditions of aging. Symptoms include increased body fat, old dry skin, loss of hair color, decreased energy, and the loss of deep healing sleep, along with the loss of muscle mass, decreased physical activity, communication, mood and energy levels, diminished healing ability, a greater risk of cardiovascular disease and lower life expectancy. We commonly call this "Aging".



SOMATOPAUSE

Somatopause is the declining mid-life phase in the human life cycle during which reduced GH levels result in a noticeable reduction in physiological function. During somatopause the cells and organs gradually dehydrate and diminish in size and function. Somatopause usually begins when people reach their mid-forties but can start years earlier. It is possible for some individuals in their forties to have IGF-1 levels usually expected of a person in their seventies and vice versa. Lifestyles apparently play an important role, along with heredity and environment. By the 60th birthday it is not uncommon to see declines from 60% to 75% of normal levels. It is no wonder that so many middle-aged people report feeling old with little vitality.

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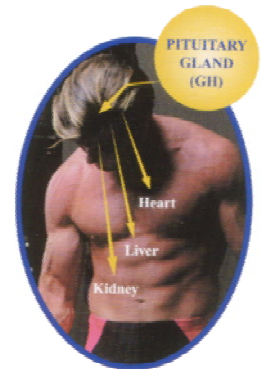
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WHAT IF GH LEVELS ARE REPLACED?

Clinical evidence demonstrates that by replacing Growth Hormone we can dramatically reverse these conditions to restore our bodies and minds to a more youthful condition. Abundant worldwide studies on injected growth hormone supplements have shown it:

- ◆ Increases Energy and Improves Oxygen Uptake
- ◆ Regenerates the body's major organs, including the Heart, Liver, Kidneys, Lungs and Spleen.
- ◆ Improves Sleep and Revitalizes the Immune System
- ◆ Decrease Body Fat, without dieting while Increases Muscle Mass, without additional exercise
- ◆ Enhances Sexual Function and Performance while Increasing libido in both men and women
- ◆ Rejuvenates Skin, Hair and Nails and Smoothes Wrinkles
- ◆ Strengthens Bones, Stimulates Tissue Repair, and Cell Replacement
- ◆ The list goes on and on.



IGF-1 AND ALBUMIN

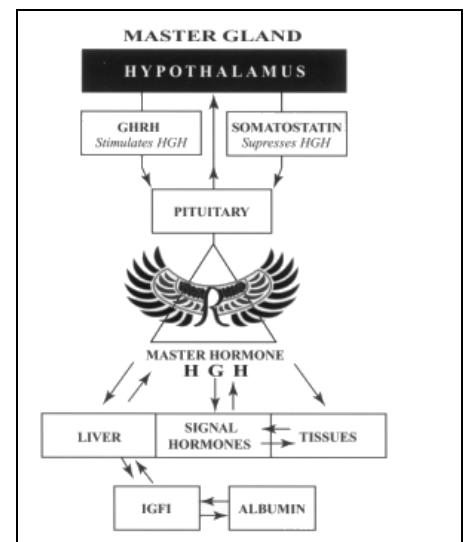
The liver manufactures IGF-1 when stimulated by GH, which in turn triggers the liver to produce albumin. Many of the beneficial effects of GH are accomplished via albumin. According to Dr. Kenneth Seaton, D.Sc., albumin is the "life factor" and one of the critical measures of our well being and longevity. Albumin is the dominant blood protein through which GH controls a vast array whose primary function is physiological balance (homeostasis).

CHARACTERISTICS OF ALBUMIN

- ◆ Viewed as the ultimate antioxidant
- ◆ Primary bio-marker of biological age
- ◆ Indicator of trend toward degenerative disease
- ◆ Essential for cell growth and renewal

FUNCTIONS OF ALBUMIN

- ◆ Regulates water metabolism
- ◆ Transports nutrients to cells
- ◆ Transports wastes from cells
- ◆ Assures proper elimination of wastes
- ◆ Synthesizes proteins
- ◆ Binds toxins and heavy metals
- ◆ Protects cells against shock
- ◆ Donates electrons to cells
- ◆ Transports and buffers excess levels of hormones
- ◆ Insures complete digestion of food



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- ♦ Vital for central nervous system development
- ♦ Stabilizes blood through turnover of red blood cells
- ♦ Prevents red blood cells from "sticking" together (zeta potential)
- ♦ Balances blood pH

GH PROMOTES

- ♦ The cell's transcription of DNA to form RNA, provided that all essential nutrients are available
- ♦ Transport of most amino acids across the cell membranes.
- ♦ RNA translation by ribosomes, promoting protein synthesis in cytoplasm of cells.
- ♦ Reduction of tissue breakdown of amino acids and protein by mobilizing large amounts of free fatty acids from adipose tissue.
- ♦ Protein "sparing" and carbohydrate "saving".
- ♦ Efficiency in controlling blood sugar utilized by cells for energy.
- ♦ Tissue repair, cell replacement, brain function and enzyme production.
- ♦ Rejuvenation of the skin, bones, heart, liver, lungs, and kidneys. Bringing organ and tissue function to youthful levels.
- ♦ The immune system, lowers the risk factors of heart attack and stroke, improves oxygen uptake and helps prevent osteoporosis.
- ♦ Natural enhancement of sexual function.
- ♦ Restoration of skin elasticity, smoothing wrinkles and rejuvenating hair and cells.

"There is no evidence suggesting that Growth Hormone Replacement Therapy causes any unfavorable long term side effects."

Dr. Rosen, M.D. and
Dr. G. Johannsson,
M.D. of University
Hospital, Goteborg,
Sweden

REPORTED BENEFITS OF GH THERAPY

The study published in the New England Journal of Medicine by Dr. Daniel Rudman in 1990 [page 30] was the first using GH as an anti-aging compound. The study divided 21 men with IGF-1 levels under 350 ng/ml of blood into two groups for a six-month period. In the experimental group, the study showed an increase in lean muscle mass, a decrease in adipose fat tissue, and an increase in vertebral bone height, as well as measurable increases in IGF-1 blood levels. The control group showed no gain in these areas. The effects of six months of growth hormone were equivalent in magnitude to the regression of aging by 10-20 years.

Dr. Edmund Chein and L. Cas Terry, MD, Ph.D., tested over 800 individuals over the age of 40, and reported in their 1995 study that GH had substantial benefits and virtually no side effects.

They reported no treatment failures. **Of great interest to Dr. Terry was the complete absence of cancer in his patients during the study.**

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Numerous clinical studies have measured and highlighted the following results after six months or more of GH therapy (*page 26*):

- ◆ Improved memory and intellectual capacity
- ◆ Improvement in Alzheimer's and Parkinson's syndromes
- ◆ Regeneration of the brain, heart, liver, pancreas, spleen, kidneys and other organs
- ◆ Improved sexual drive and performance
- ◆ Increased fertility, sperm production and ovulation
- ◆ Enhanced immunity and resistance to infection
- ◆ Faster injury healing, including wounds and fractures
- ◆ Hair re-growth and color restoration
- ◆ Sharper vision
- ◆ Improved exercise tolerance and performance
- ◆ Increased muscle mass without exercise
- ◆ Reduction of excess cellulite and fat
- ◆ Increased energy, strength and stamina
- ◆ Reduction of high blood pressure
- ◆ Increase in HDL cholesterol
- ◆ Decrease in LDL cholesterol
- ◆ Strengthening of bones
- ◆ Reversal of osteoporosis
- ◆ Improved sleep (especially deep healing sleep)
- ◆ Elevation of moods and reduction of depression
- ◆ Improved skin elasticity and thickness
- ◆ Smoothing and reduction of facial wrinkles
- ◆ Improved mineral balance

In essence, turning back the biological clock

THE DIFFERENCES BETWEEN INJECTED AND SUBLINGUAL GH

Injectable GH has been used for hormone replacement for many years. This is painful and very costly. In addition there are valid concerns over side effects with patients receiving these unnaturally large doses. These doses can lead to a complete shutdown of the natural production of GH, leaving the patient dependent on injections (*see graphs, pages 8-9*).

The alternative is Regenes Health Oral Spray GH for which there are no reported complications. **Effective oral spray GH promotes an increase in IGF receptor sites, increasing effectiveness and eliminating the concern for elevated IGF levels.** A six month commitment to the program is suggested, although many people will notice effects within a few weeks. At a very affordable price, now almost anyone can now enjoy the benefits of renewed Growth Hormone levels.

"Results in the use of sublingually administered Growth Hormone (Regenes Health 1, Power and Pro) in eighty patients over a two years period: all but two (one with the highest endogenous IGF-1) were otherwise consistent in demonstrating an increase in energy (including those with Chronic Fatigue Syndrome) and an increase in mental alacrity (including Alzheimer's, Senile Dementia and depressive reactions). There was evidence of Hormonal balancing with amelioration of PMS and in one case disappearance of long term Endometriosis. There was a marked increase in sense of well being, including two HIV positive patients, one of whom also evidenced a dramatic decrease in viral load."

Dr. F. Pearl McBroom, M.D.

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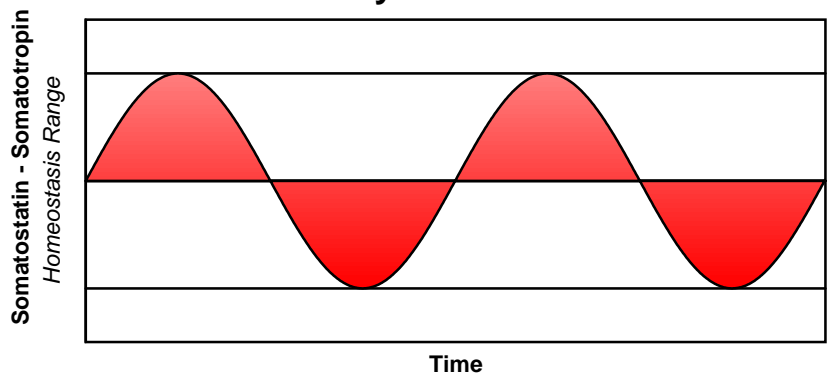
REGENESIS PRO 500

Our Flagship product has been used by thousands of individuals and clinics throughout the world. Regenesi s Pro 500 contains authentic recombinant growth hormone (rhGH) in a breakthrough polymer matrix which is absorbed into the body. Regenesi s GH is identical to the growth hormone your body produces. Oral ingestion is very safe and efficient and allows maximum utilization to benefit the body. The pituitary releases HGH in parts per billion and even parts per trillion. Regenesi s GH contains 1/125 to 1/1000 the concentration found in the hGH injections. Regenesi s GH (low dosage oral GH) was designed to mimic the body's own secretions of HGH. **Regenesi s GH is where science mirrors nature.**

HIGH DOSAGE/LOW FREQUENCY VS LOW DOSAGE/HIGH FREQUENCY

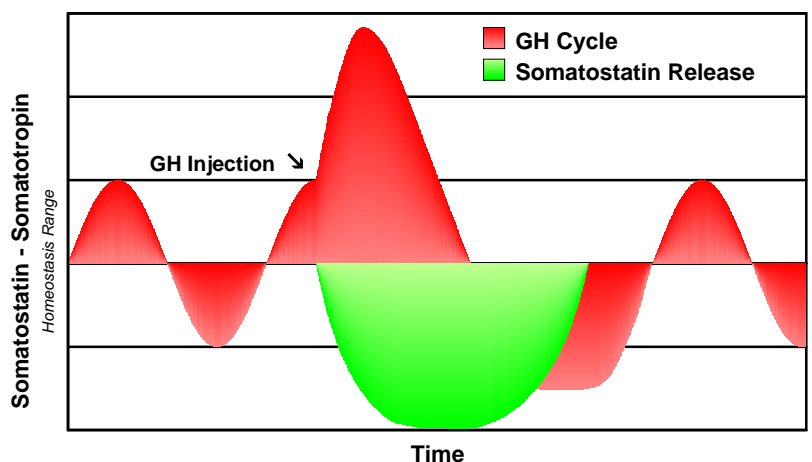
Normal GH Wave - HGH Production and inhibition created by the response of the hypothalamus in reading HGH levels in the bloodstream. The centerline is optimum efficiency of the body with upper and lower parameters in which the body functions called homeostasis. The body stays within these parameters by the production of HGH and inhibitors. This function is carried out by the pituitary gland.

Normal Cycle of GH Release



Abnormal Cycle GH Injection Therapy - GH is injected in the body in large dosages usually International Units. This high dosage is read by the hypothalamus as too much GH in the body and shuts down the pituitary on the anterior (front) lobe. The posterior (back) lobe goes into high production of GHIH, Growth Hormone Inhibiting

Abnormal Cycle GH - Injection Therapy



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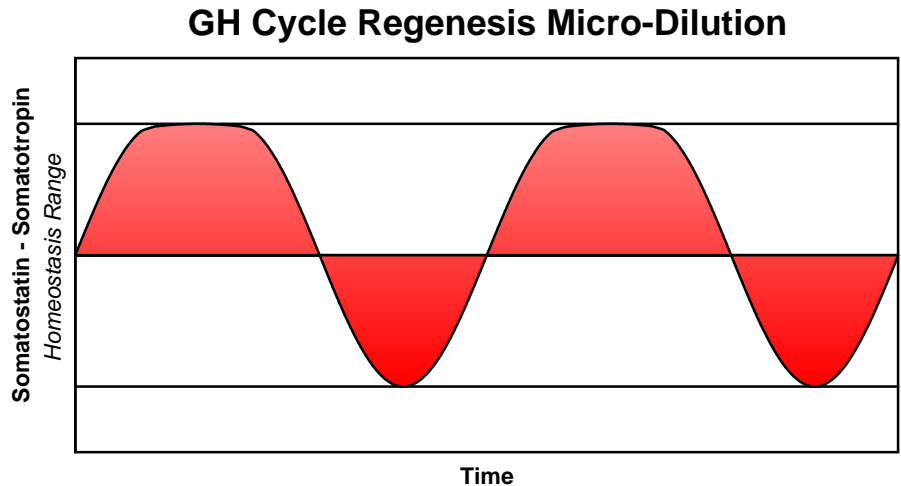
Hormone. This is the body's reaction to the imbalance of HGH in the body. The body has now exceeded both the upper and lower limits of homeostasis. Receptor cell saturation, pituitary gland "burnout" and dependency on continued injections are all possible.

Enhanced Cycle of Micro Dilution Therapy -

Oral spray GH is administered inside of the cheek. The low level GH does not create a spike in the GH level

of the body but lengthens the GH pulse so that GH is at higher levels in the body, longer than normal. This has many positive effects on the body. The pituitary continues producing GH in its normal cycle. The anterior pituitary is not shut down by the hypothalamus. The body does not suffer

from rebound effect of the injections (A lack of GH present in the body for a period of time). There are no known side effects to the micro dilution therapy. There is no need for the cycling of a micro dilution and no possibility of receptor cell saturation, causing the receptor cell to shut down.



THE FINEST OPTION AVAILABLE

Regeneration GH was designed to stimulate the production and release of Growth Hormone. Evidence suggests Regeneration GH also enhances the absorption of the resulting growth factors. Over a period of time (typically 3-9 months) patients will notice a drop in IGF-1 numbers while seeing positive results from Regeneration GH spray. Since HGH is responsible for the regulation of IGF-1 in the liver, scientists and manufacturers assume anything that increases IGF-1 levels must also be increasing HGH levels. There is much evidence this is not the case.

Dr. Rashid Buttar has observed significantly lower than expected IGF-1 levels among high performance athletes. Athletes have lower serum glucose levels and a greater sensitivity to insulin. As well, athletes are biologically (physiologically) younger than sedentary people. He states "Efficacious hGH therapy does not increase IGF-1 levels".

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In fact there is "An inverse correlation of IGF-1 and hGH efficacy".

Dr. Buttar states that effective hGH replacement therapy will increase IGF receptor sites. The increase in IGF receptor sites leads to an increase in IGF binding and a lowering of circulating serum IGF-1. This is what we have observed in patients taking Regenesis GH over the years as well.

LIFE EXTENSION AND LIFE QUALITY

What if thousands of doctors told you that you could live to be a healthy 100 to 120 years of age? The A4M (American Academy of Anti-Aging Medicine), LEF (Life Extension Foundation, along with others such as ACAM are focused entirely on health, longevity and anti-aging. These associations believe that the effects of aging can be addressed with proper precautions and that human potential for life has now been expanded to more than 120 years.

The discovery of GH replacement may well allow human beings to live an additional 20-30 productive, active and vital years of life to enjoy with their families. Which begs the question, what would you and your patients do with an extra 5, 10, or 20 years of healthy, vibrant, youthful life?

"You go to medical school and you want to save the world and eventually it's....it's not as effective as we thought it would be. All we're doing is managing disease. Of course, it's incredible technology. But more and more, we doctors are becoming dissatisfied with our abilities to heal. And at some time in our lives, we come to ask ourselves: "What am I trying to do here?"

Eve Bruce, MD

YOUR PATIENTS WILL KEEP COMING BACK FOR MORE!

Clinical studies show - As hGH is increased in the body, your patients get what they want and need.

Experience shows - patients come back for additional product, month after month. With little professional contact (we do recommend a staff member follow up), ease of use and progressive positive results, patients are happy to continue with Regenesis GH for years.

Contact us now, and begin enjoying the benefits of Regenesis GH oral spray, and for your professional pricing. Ask about our "No-Stock" programs for your office!

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SUGGESTED USAGE

TESTING FOR GH

IGF-1 was considered the standard for measuring levels of GH in the body. This is no longer the case. However we still recommend testing for IGF-1 as a baseline. During initial treatment the majority will record a substantial increase in their IGF-1 levels; with about 20% showing a decrease in levels even while reporting tangible health improvements. **After a period of 3 to 9 months most patients will show a drop in circulating serum IGF-1 as the number of receptor sites increases.**

Regardless of the scores, most every one taking Regenesis GH for a month or longer reports visible evidence of improvement in most aspects of their health (page 15).

Along with IGF-1, consider a blood and hormone panel such as the following: pregnenolone, thyroid (T3, T4, TI, TSR, TBG), progesterone, estrogens (estriol, estradiol, estrone), testosterone (free-, dihydro-, total-), DHEA, PSA and CA-125.

SYNERGISTIC NUTRITION

Regenesis GH works best when used with synergistic nutrition. Supplements, which support GH levels, are of three primary categories: precursors, stimulants and synergists.

Precursors are the foundation "raw materials" from which the body produces its own GH. Some precursors are the amino acids glycine, tryptophan, arginine, ornithine, lysine and glutamine.

Stimulants directly or indirectly are responsible for the body's increased ability to stimulate GH. Niacin (vitamin B-3) is a safe stimulant of GH, best used with other nutrients such as amino acids, vitamins and essential fatty acids. The suggested optimal dosage is 50-200 mg. 2-3 times per day.

Synergists are substances, which enhance the effects of, or work together with, GH by performing similar functions. Potent synergists of GH include low dosages of hormones such as melatonin and DHEA which, with GH, seem to enhance oxidation and energy efficiency within the cells. This energetic renewal is theorized by some to assist in improving protein synthesis of the DNA, thereby regenerating cells, tissues and organs. The oxidation rate can be verified through tissue mineral analysis of the hair, blood and saliva.

Dr. Edmund Chein monitored 202 patients on GH at the Life Extension Institute in Palm Springs and observed improvement in muscle size, strength, and exercise levels in more than 81% of his patients. He also observed improvement in joint flexibility in more than 71% of patients.

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FACTORS THAT ENHANCE PRODUCTION AND UTILIZATION OF GROWTH HORMONE

As promoters of anti-aging techniques, we believe in a holistic approach to health and wellness. Following are approaches we feel will promote a long, healthy and energetic life.

Detoxification - Getting the toxins out is foundational in aiding our bodies ability to restore itself. We are assaulted by a variety of toxins in the air we breathe, the food we eat, and many of the products that we use on our bodies every single day. These toxins are stored in our internal organs and tissues greatly affecting our bodies ability to heal itself. We recommend taking a very aggressive approach to detoxification.

"I think that a lot of aging can be explained by deficits in growth hormone."

Greg Fahy, Ph.D.

Nutritional Supplementation - Today the four leading causes of premature death in the U.S. are heart disease, cancer, stroke, and diabetes, all of which are lifestyle-based, degenerative diseases. None of those diseases are infectious and, according to current research, all of them can be prevented by a healthy, balanced diet and lifestyle. Centuries of very aggressive commercial farming on this planet has virtually destroyed and depleted our top soil which is the only place we can access the majority of the trace minerals and nutrients our bodies require in order to be successful at preventing disease.

Dr. Daniel Rudman published his findings in the New England Journal of Medicine on GH and its affect on the aging process. Higher IGF-1 levels due to increased GH stimulation affect every cell in the body. He studied a group of men ages 61-81 and observed a biological reversing of aging from 10-20 years within six months of taking, at that time, injectable GH.

[see page 30]

Hormone Supplementation - The decline in hormones is directly related to the adverse signs of aging. Those of us with naturally lower amounts of certain hormones age much faster and more visibly than those of us who by reason of genes or high exercise level maintain a higher level of hormone production for a longer period of time. This loss of hormones with age is similar to that seen with menopause. Natural supplementation beginning at the age of 30 and up may allow you to slow or even stop the aging process. Of course Growth Hormone is the ultimate anti aging compound on the planet at this time.

Deep Restorative Sleep - Deep sleep coincides with the release of growth hormone in

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children and young adults. Our cells also show increased production and reduced breakdown of proteins during deep sleep. Since proteins are the building blocks needed for cell growth and for repair of damage from factors like stress and ultraviolet rays, deep sleep may truly be "beauty sleep." Activity in parts of the brain that control emotions, decision-making processes, and social interactions is drastically reduced during deep sleep, suggesting that this type of sleep may help people maintain optimal emotional and social functioning while they are awake.

Consistent Exercise - Vigorous exercise and strength training at least three times a week. Try to vary your exercise from day to day with brisk walking, swimming, weight training, dancing, yoga and active sports. Strength exercises help the body to produce its own HGH and aerobic exercises support the cardiovascular system. It is best to exercise when blood sugar levels are normalized (at least 2½ hours after eating). Studies have shown that consistent exercise will also sharpen the mind and balance emotions.

Balanced Nutrition - Approximately 40% complex carbohydrates, 30% protein, 30% fat. Consume organic raw or lightly cooked fresh foods: fruits, vegetables (especially green leafy types), grains, nuts, seeds; fish and poultry. Living whole foods are always best. Where possible, eat organic meats. Limit consumption of red meats and processed non-living foods; certain fats and oils, sugars, salt and alcohol. Utilize synergistic vitamins, minerals, essential fatty acids and amino acids. Drink purified (reverse osmosis) water. A day of liquids only (juicing) will promote healing, cleansing, and organ function.



And - Daily sun bath (without glasses) with as much exposed skin as feasible for 10-20 minutes. Evidence shows that daily sun exposure may be as important to maintaining optimal health as any other component. Practice deep breathing techniques in clean air and utilize relaxation methods such as meditation.

NUTRITION AND HORMONES

Individuals with low cholesterol levels (below 160) especially need fats and oils to make hormones. The best sources are unrefined olive, coconut, whole fish, flax, black currant, evening primrose, borage, hemp and butter. Evidence shows that is the oxidation of the arteries and cholesterol, not high cholesterol levels that cause circulatory disease. Too low of cholesterol levels may lead to hormonal imbalances, decreased brain function (dementia, Alzheimer's) and other health deficiencies.

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FOR CHILDREN

Children should not be given Regenesis GH unless it has been prescribed by a doctor who has determined, through formal diagnosis which includes testing IGF-1, that they require it. Regenesis GH is convenient, effective and safe for children, however there are no clinical studies on children with serious growth disorders.

HOW TO TAKE REGENESIS GH

The most effective times to take Regenesis GH are approximately 20 minutes before meals, immediately before workouts (spray once every 20-30 minutes during exercise) and immediately before bedtime. **Exercise & bedtime are the most important times.**



The recommended *maintenance dosage* is 3 sprays per day, once upon rising and 2 just before retiring for the evening. **However most users will benefit from an additional spray in the mid afternoon and before their exercise program.** Many users leave Regenesis GH on their night stand (out of direct sunlight) as a reminder. **Most users spray 6 times per day during their first month (many stay with 6 sprays).** Dosages greater than 8 sprays per day achieve little additional value for the user. For optimal results spread the sprays out during the day as frequency is as important as quantity (before breakfast, midmorning, before lunch, early afternoon, late afternoon, before dinner and 2 before bed). Regenesis GH is more effective when avoiding the period: 20 minutes before to 2½ hours after eating. Regenesis GH may be administered 7 days per week. Results may be better by not using Regenesis GH for one week every 3 months.

WHERE TO SPRAY REGENESIS GH?

We have found that the best place to spray it is on the inside of the cheeks holding the spray in the mouth for 1-2 minutes. If it is sprayed under the tongue it is likely to stimulate saliva flow which the patient may be inclined to swallow. Spraying it on the inside of each cheek, covers a wide area, not stimulate saliva flow, and the patient will be able to retain it in their mouth for a few minutes while it is being absorbed.

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HOW LONG WILL IT TAKE TO SEE RESULTS FROM REGENESIS GH?

Some people notice improvements within a few weeks, such as increased energy, better sleep, and better mood. However for others it takes longer. **A trial period of at least six months is recommended.** Structural improvements in skin and hair definitely take longer, months and not weeks. Remember that the initial benefits occur "on the inside" before eventually manifesting "on the outside". If you practice a healthy lifestyle while using Regenes GH, you are likely to see results faster.

EXPECTATION LIST

Expectations when using Regenes GH, the World's Finest Oral Spray Growth Hormone

Expectations for the first month

- Increased energy levels
- Better, sounder sleep
- Improved stamina
- Vivid dreams
- Optimistic, youthful attitude

Expectations for second month

- Improved muscle tone
- increased strength
- Improved skin tone
- Improved nail growth
- Better digestion
- Weight loss
- Improved vision
- Enhanced sexual function

Expectations for third month

- Improved mental processes
- Enhanced productivity
- Faster wound healing
- Hair re-growth
- Increased libido
- Increased muscle size
- Faster recovery from muscle soreness
- Reduced PMS symptoms
- Greater body flexibility
- Reduced joint & muscle pain
- Improved weight loss and reduction of inches

Expectations for fourth month

- Heightened improvements for all previously listed items
- At times improvements may seem to diminish or plateau
- Rejuvenation is still in process
- Benefits should resume with continual improvements

Expectations for fifth month

- Improved skin texture and appearance
- Skin thickening and greater elasticity
- Reduction of wrinkles
- Thickening of hair, with a shiny, healthy appearance

Expectations for sixth month

- Diminished cellulite
- Improved body contour
- Excellent exercise tolerance
- Improved cholesterol and triglyceride profile
- Lowered blood pressure

Not everyone will receive ALL the expected results during the months noted.

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PERSONAL SUPPORT

The key to keeping a person inspired about their Regenesi s GH rejuvenation program is frequent communication to monitor their progress. Prior to use, record objective (i.e.: blood work) and subjective (aches, pains, etc.) for each patient. Some people may not notice improvement, yet when asked specific questions about their conditions, are reporting measurable evidence of their improvement. Most people are enthusiastic and reporting very positive results from their rejuvenation program. It is important to communicate that it is through long-term usage (at least six months to a year) of GH that the most important benefits, such as organ and cellular regeneration, occur.



SIDE EFFECTS

There are no known side effects from Regenesi s GH. However, when the body increases its vital energy, it may begin to heal its weaknesses. In holistic medicine, when the body begins to heal old health issues, it is called a healing crisis or retracing. The body may expel toxins stored in fat tissue and organ systems.

This elimination process can cause temporary conditions such as headaches, skin irritations, mild anxiety, heart palpitations, and/or viral outbreaks, potential signs that the body has begun to heal itself.

It is important to remember that as the body begins to repair itself, it requires more water intake to assist in the elimination of toxins. The average person should drink at least six (6) to eight (8) glasses of fresh, non-chlorinated, non-fluorinated water a day.

Any powerful supplement has the potential to push a dormant health condition to the surface. For example, heavy metals, pesticides, chemicals, drugs, parasite waste, viruses, bacteria, yeast, etc. may lie dormant in the organs and fatty tissue until the body has the energy to eliminate them.

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CLINICAL STUDIES

F. Pearl McBroom, MD Inc.

Internal Medicine, Cardiology and Preventive Medicine

3/18/00

PRELIMINARY CLINICAL OBSERVATIONS ON THE USE OF CENOGENESIS [renamed Regenes Plus]. A 320 NG PER SPRAY SUBLINGUAL ORAL GROWTH HORMONE PROVIDED BY REGENESIS

In February, 2000 F. Pearl McBroom, MD, Internist, Cardiologist, Preventive Medicine Specialist, Graduate of the University of Chicago, Columbia College of Physicians & Surgeons, UCLA and University of Southern California, began noting clinical responses to the use of Cenogenesis. It is the highest potency oral Growth Hormone product provided by Regenes, a pioneer in the field of sublingual Growth Hormone. It provides delivery of 320ng per spray of Growth Hormone delivered orally with maximum suggested 3-4 times daily. Dose is dependent on the initial Insulin Growth Factor (IGF-1) or Somatomedin C Endogenous Growth Hormone levels.

There were ten patients observed between January and March, 2000 who started on Cenogenesis on dates indicated below:

J.C. -54 years old- caucasian female, Somatomedin C (IGF-1) level 167 ng/ml (114-492 normal range). A former gifted schoolteacher with Chronic Viremia and Chronic Fatigue Syndrome and Fibromyalgia, she was unable to work in the past 4 years, during which time she had gained 30 pounds. Within one week on Cenogenesis she lost 10 pounds. During the ensuing month, despite her continued complaint of Chronic Fatigue and Fibromyalgia, she planned and administered a huge birthday celebration gala for her mother, took on a 5 day per week child sitting job with 2 children and drove round trip to San Francisco. These activities represented a major feat in energy requirement for her despite her symptom chronically.

O.P. -43 years old- negro male chauffeur, IGF-1 140 ng/ml (normal 90-360) with Chronic Viremia, Chronic Fatigue Syndrome, residuals of left knee endoscopic surgery and left ankle sprain. Despite these syndromes, he was actively and effectively functioning as a full time chauffeur. Within 24 hours of starting Cenogenesis on January 6, 2000, his energy level soared and in March, 2000 not only completed the L.A. City Marathon but coached another entrant, enabling him to complete the Marathon as well.

M.P. -59 years old- caucasian female exhibiting artist, IGF-1 (Somatomedin C) level 126 (normal 116-270) with severe depression and fatigue was started on Cenogenesis on February 10, 2000. Within two weeks she was in high tone and energetic in a fashion she had never experienced. Her painting artistry was directly inspired.

S.T. -63 years old - minister, Somatomedin C (IGF-1) 94 (normal range (116-270)) with complaint of fatigue and depression. Started on Cenogenesis on February 16, 2000. Within 48 hours she notified us of her resurgence of energy and improved sense of well being.

A.H. -89 years old - black female, mother of S.T. (see above), whose chief problem was Alzheimer's Syndrome. At Dr. McBroom's suggestion S.T. gave her mother one spray (320 ng/spray) per day beginning February 16, 2000. Within 24 hours the patient, who had been

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incoherent, was speaking full sentences and has continued to do so now for 2 months. She is the rage of her community. Members of her church could not believe her transformation. Dr. McBroom has seen dramatic improvement in patients with Alzheimer's Syndrome and Senile Dementia taking Regenesis products.

J.C.R. - 38 years old- negro female, IGF-1 (Somatomedin-C) 335, complaining of Hypomenorrhea with Menses since onset only 3 or 4 times per year with high hormone levels. She was started on Regenesis Pro August 26, 1999. She became pregnant approximately 4 1/2 months after starting Regenesis Pro. She terminated the pregnancy March 13, 2000 and consequently developed postpartum depression. When she was seen on March 16, 2000, she was tearful, anxious, and fearful. She was given one spray of Cenogenesis in the office and was treated for acupoint balancing. She left the office in high tone and good spirits. She has continued so in the past week.

D.M. -37 years old- black female with severe Dysmenorrhea starting 2-5 days before Menses. She began having mild Dysmenorrhea 5 days before the Menses and was given one spray of Cenogenesis the evening of 5th day before Menses, one spray the fourth day before Menses and two sprays the third day before Menses. Ordinarily she would be having profound cramping by then. However, with the Cenogenesis, she has thus far had no cramps and will continue to be observed and added to the Cenogenesis study observations.

L.M. -43 years old- black female with severed cystic mastitis of the breast was started on one spray of Cenogenesis twice daily on March 18, 2000 and immediately noted amelioration of the usual discomfiture in the right breast. She is to be added to the Cenogenesis study observations.

A.J. -51 years old - caucasian female, Somatomedin C (IGF-1) level 117 (90-361 normal range) has history of Hypothyroidism and Menopausal Syndrome with hot flashes, emotional liability, and reduced energy. She was started on Cenogenesis on January 13, 2000, replacing Regenesis Pro which together with Porcine Thyroid had normalized her Thyroid function, and removed the Arrhythmia associated with a prolapsed mitral valve. The addition of Cenogenesis resulted in relief of the menopausal symptoms and an increase in overall energy and sense of well-being. She continued to maintain absence of Arrhythmia of the Mitral Valve Prolapse.

J.L. -42 years old - caucasian female, Somatomedin C (IGF-1) level 179 (normal range 116-270). She had lived with a financially and emotionally stressed environ and associated Chronic Viremias and Chronic Fatigue Syndrome. She started Cenogenesis February 1, 2000 and noted immediately an increase in her capacity to relax and in her overall energy level and sense of well being, which were greatly augmented. She created financial breakthroughs and vacation travel. She was thoroughly enrolled in continuing Cenogenesis, which she has done.

A.P. - 84 years old- caucasian male, IGF-1 (Somatomedin C) on March 12, 2000, 66 ng/ml (normal range 71-290). History of Shingles (Herpes Zoster) with chronic painful residuals in the past year improved with Physiotherapy but unresolved. Started on Cenogenesis March 12, 2000 and within 24 hours was exuberantly extolling his newfound energy, noteworthy strengthening of muscle tone, and attending decrease in Shingle residual discomfiture. He looks forward to continued benefits from Cenogenesis.

F. Pearl McBroom, MD

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WAVELAND WELLNESS CENTER

1346 W. WAVELAND AVE. CHICAGO, IL 60613

**MICRO-DILUTION ORAL GROWTH HORMONE SUPPLEMENTATION:
A DOUBLE-BLIND CONTROLLED RESEARCH STUDY ON REGENESIS 1**

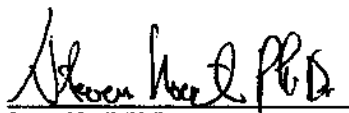
Summary-

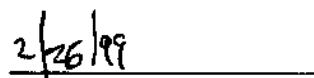
Growth Hormone (somatotropin) is the master regulatory hormone in the body, produced by the anterior pituitary gland. Growth hormone therapy has been used to combat age-related growth hormone decline. Recently an oral delivery system was developed that utilizes a unique matrix to deliver growth hormone to the body through the oral mucosa. This delivery system provides the body with micro-doses of growth hormone designed to mirror the pituitary's natural growth hormone secretions.

Current Research

A double-blind controlled research study assessing IGF-1, quality of life and times ability was recently completed. The direction in movement of hormone levels being brought back to youthful and regenerative levels is significant in of itself. The results of the chem 24/chem 25 tests show the cholesterol, HDL, LDL returning to normalization. The results of the study show test patients taking Regenes Pro had significant results in the body with a rise of 40% in IGF-1 levels compared to 13% in Placebo patients, 31.5% rise in DHEA with a 28% drop in Placebo. Testosterone levels elevated 18.5%.

After compiling supporting data of the double blind study, there is a significant physiological change with the patients who had taken Regenes Pro. The levels of IGF-1, Testosterone, and DHEA, along with the changes in the lipids, show that the patients consistently evidenced marked progressiveness towards balance. The resultant physiology of the patients was a gentle response to the micro-dilution oral spray. Regenes Pro returned the body to a higher metabolism with greater efficiency and a more youthful level of chemistry. The subsequent blood draws show marked consistency of rise in chemistry for the patients and then setting a higher threshold for the level of homeostasis of the body.


Steven Novil, Ph.D.


Date

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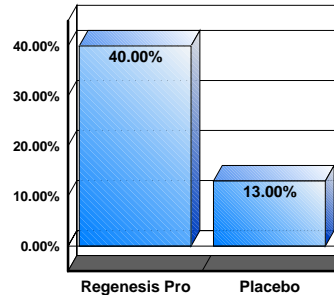
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REGENESIS DOUBLE BLIND STUDIES Conducted at Waveland Wellness Center

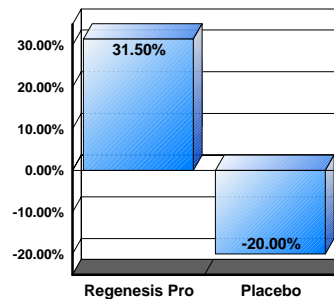
IGF-1

* Mean Value IGF-1 in Placebo raised 13 %; Regenesis Pro raised 40 % in first 2 weeks of study



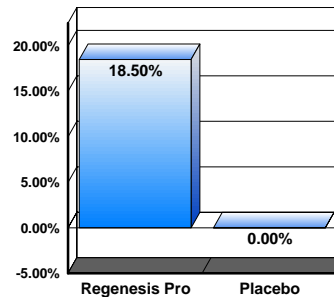
DHEA

*Mean Value DHEA in Placebo lowered 20 %; Regenesis Pro raised 31.5 % in first 2 weeks of study



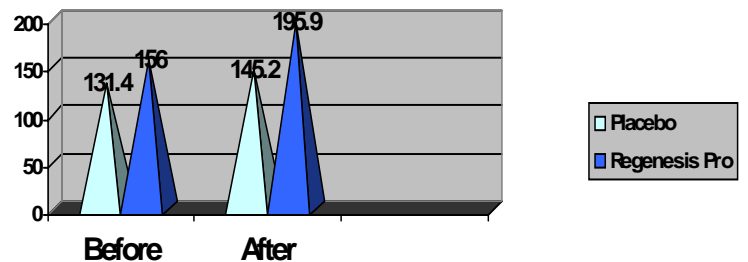
TESTOSTERONE

Mean Value TESTOSTERONE in Placebo (no test results); Regenesis Pro raised 18.5 % in first 2 weeks of study



IGF-1

*Mean Value IGF-1 in Placebo raised 14 points; Regenesis Pro raised 41 points



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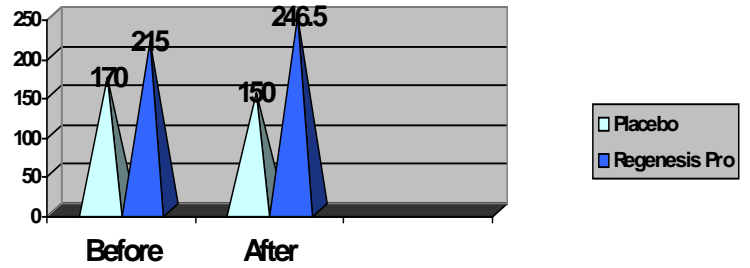
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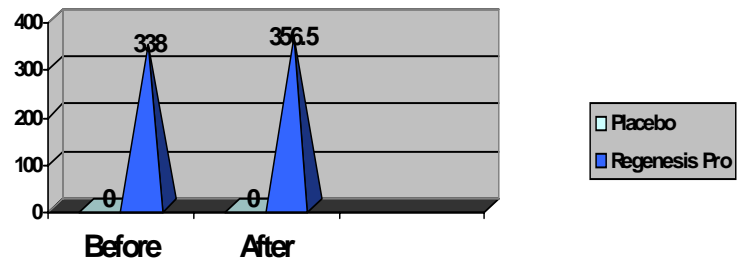
DHEA

*Mean Value DHEA in Placebo lowered 20 points; Regensis Pro raised 31.5 points



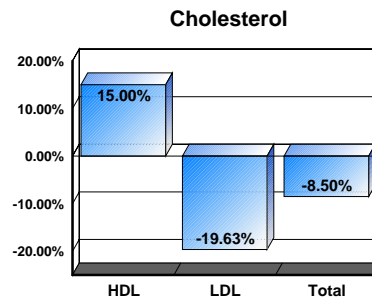
TESTOSTERONE STUDY OF MALES Ages 46-76

*Mean Value TESTOSTERONE in Placebo (no test results); Regensis Pro raised 18.5 points



CHOLESTEROL

* Mean Value of High Density Lipos raised 15%
 * Mean Value of Low Density Lipos lowered 19.63%
 * Mean Value of Cholesterol lowered 8.50%



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REGENESIS 1

Clinical Results

IGF-1 (insulin growth factor - 1) Preliminary Data

Change: NONE - 0 SOME - 1 MODERATE - 2 GOOD - 3 GREAT - 4

Subject Init	Dr. Init	AGE	SEX	Diagnosis	First Test	Retest	IGF RESULTS 2nd Test / First Test	Result IGF-1	Percent Change	Comments / Results
FI	RF	77	F	Fatigue	9/1/97	1/20/98	129 ng/ml - 85 ng/ml	44	52%	4
SO	MM	58	F		1/1/97	11/15/97	53 ng/ml - 55 ng/ml	<2>	<4>	
BW	SG	62	M		6/7/97	8/6/97	199 ng/ml - 151 ng/ml	48	32%	3
JC	PM	52	F	Chronic Fatigue	4/10/97	10/24/97	185 ng/ml - 167 ng/ml	18	11%	
GG	PM	48	M		1/30/97	4/21/97	129 ng/ml - 142 ng/ml	<13>	<9%>	
MH	PM	45	F	Hormonal Imbalance	5/5/97	11/21/97	58 ng/ml - 129 ng/ml	71	55%	
CD	PM	52	F	Fatigue	4/8/97	5/12/97	235 ng/ml - 135 ng/ml	100	74%	3
KL	PM	37	F	Fatigue	3/27/97	9/2/97	279 ng/ml - 208 ng/ml	71	34%	3
RN	PM	55	M	Hypothyroidism	4/5/97	6/5/97	195 ng/ml - 72 ng/ml	123	170%	4
GG	PM	48	M	HIV Positive	4/21/97	10/30/97	172 ng/ml - 142 ng/ml	30	21%	3
JC	PM	47	F	Fatigue	4/10/97	10/24/97	185 ng/ml - 176 ng/ml	9	5%	2
MC	PM	52	M	Fatigue	Feb-97	7/22/97	168 ng/ml - 84 ng/ml	84	100%	4
JC	PM	52	F	Severe Fatigue	4/10/97	10/24/97	185 ng/ml - 167 ng/ml	18	11%	2
KL	PM	37	F	Depression / Fatigue	3/27/97	9/2/97	279 ng/ml - 208 ng/ml	71	34%	3
MH	PM	45	F	Hormonal Imbalance	5/5/97	11/21/97	58 ng/ml - 129 ng/ml (off 2 wks prior to retest)	<71>	<55%>	2
MC	PM	52	M	Fatigue	2/1/97	10/22/97	168 ng/ml - 84 ng/ml	84	100%	4
JM	JM	74	M	Fatigue	6/20/97	7/25/97	282 ng/ml - 199 ng/ml	83	41%	3

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KP	JM	72	M	Fatigue	8/29/97	10/1/97	225 ng/ml - 124 ng/ml	101	81%	3
PM	MM	71	M	Fatigue			177 ng/ml - 187 ng/ml	<10>	<6%>	
GA	MM	43	M	Insomnia	4/1/97	7/31/97	158 ng/ml - 184 ng/ml	<26>	<15%>	2
RD	MM	41	M	Fatigue	4/1/96	2/1/97	289 ng/ml - *IGFBP-3 2.1	189	189%	4
BB	RD	41	M	Fatigue	11/1/96	1/1/97	140 ng/ml- 15 ng/ml	135	800%	4
AJ	RD	43	F	Fatigue	8/1/97	10/30/97	210 ng/ml - 218 ng/ml	<08>	<5%>	2
BW	SG	62	M	Fatigue	6/7/97	8/7/97	199 ng/ml - 151 ng/ml	48	31%	3
SO	MG	58	F	Fatigue	10/1/97	11/15/97	53 ng/ml - 55 ng/ml	<2>	<4%>	2
SF	PM	81	M	Fatigue	6/20/97	9/24/97	82 ng/ml - 80 ng/ml	2	1%	3
BF	PM	82	F	Fatigue	6/20/97	9/24/97	296 ng/ml - 285 ng/ml	11	3%	3
PF	PM	50	F	Fatigue	5/1/97	7/1/97	100 ng/ml- 40 ng/ml	60	250%	2
RF	PM	49	M	Hormonal Imbalance	5/1/97	7/1/97	140 ng/ml - 100 ng/ml	40	405	4

Clinical Results 2-20-98

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REGENESIS PLUS GROWTH HORMONE STUDY:

Babak Parisan MD of the Bushard Medical Group clinically evaluated and assisted in a six-month study involving the administration of a polymer matrix oral spray Recombinant Growth Hormone delivery system. 200 healthy patients were screened and tested (112 females and 88 males). IGF-1 testing is presently the standard accepted protocol for evaluating the level of Growth Hormone in the blood.

Patients were pre-examined to determine a baseline IGF-1: 114.26 ng/ml in females (average age 51) and 135.22 ng/ml in males (average age 48). No change in diet was advised, however it was noted that all patients ate an average of 3 meals per day with approximately 3000 calories.

Testing began with a prescribed dosage of 3 sprays in the morning within one hour of awakening (equaling approximately 1000ng of HGH) and 3 sprays in the evening immediately before retiring (totaling approximately 2000ng of GH per day, seven days a week).

30 days after inception, testing showed that patients' IGF-1 levels were elevated 30% over baselines: 149.85 ng/ml in females and 176.31 ng/ml in males.

After 60 days, IGF-1 levels were tested again and shown to be 53% over baselines: 175.63 ng/ml in females and 209.59 ng/ml in males. At the end of the 6 month study, IGF-1 levels had increased over 102% over baseline in females (232.12 ng/ml) and 109% over baseline in males (284.05 ng/ml).

Cholesterol levels were diminished in 94 patients by an average of 14.8%, and triglyceride levels were also reduced by 31%. Improvements were noted in mental stability, muscle accretion, weight reduction, energy level, libido, epidermis rejuvenation, and reacquired hair color and density. In all 200 patients no adverse side effects were reported or observed.

Results indicate the following: The study suggests that the use of the 191 amino acid growth hormone molecule administered in a sublingual application is an effective method for encouraging and promoting the rejuvenation of cellular tissues.

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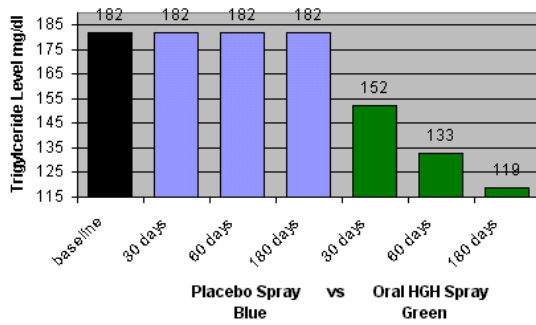
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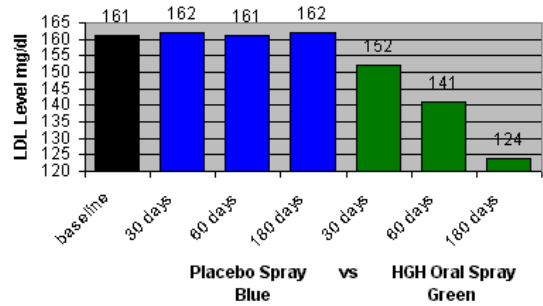
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THE ORIGINATORS OF ORAL SPRAY GROWTH HORMONE

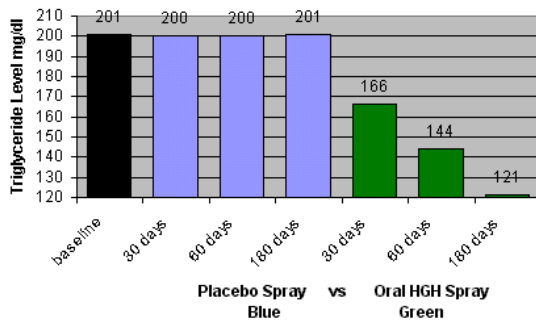
TRIGLYCERIDE LEVELS - MALE



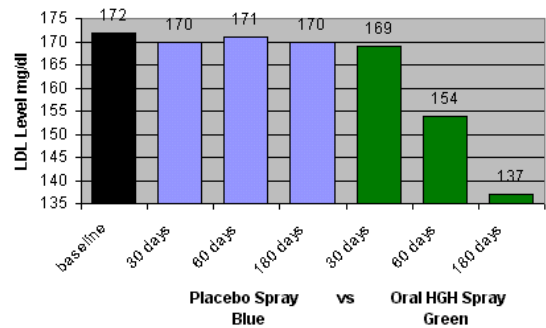
LDL LEVELS - MALE



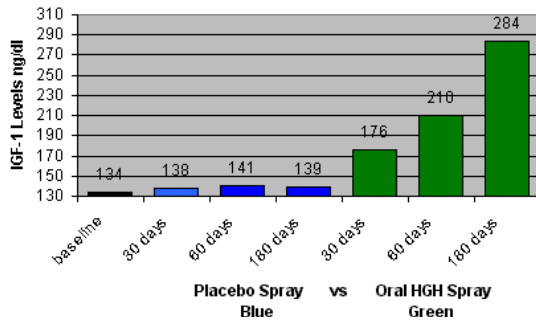
TRIGLYCERIDE LEVELS - FEMALES



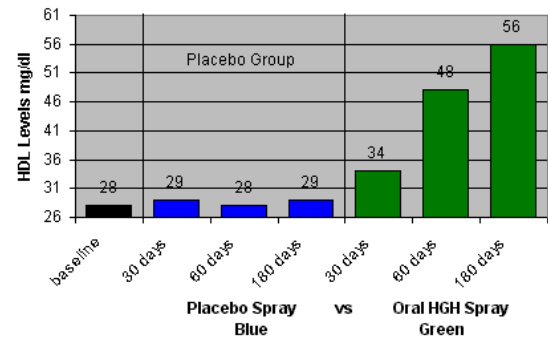
LDL LEVELS - FEMALES



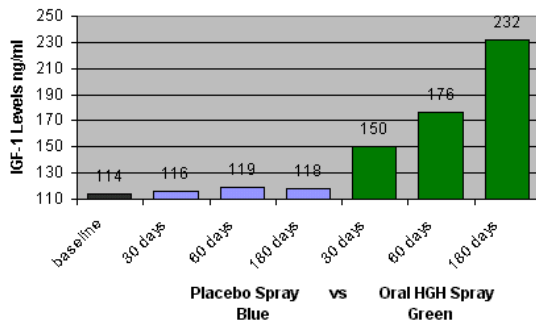
IGF-1 LEVELS - MALES



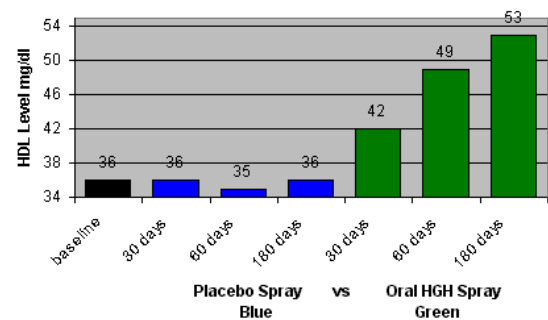
HDL LEVELS - MALES



IGF-1 LEVELS - FEMALES



HDL LEVELS - FEMALES



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REGENESIS REPORTS SHELF LIFE TEST RESULTS
REGENESIS PLUS ORAL SPRAY GH

May 22, 2002

To: Regenesi s Customers

Subj.: Shelf Life test

The following is the result of Regenesi s Plus testing for shelf life:

Sample ID:	120501320
Growth Hormone level:	320ng /per spray
Lab Number:	M-5568-1
Shelf Life:	5.0

No deterioration in the level of GH was detected beyond analytical error (<10%) over a period equivalent of 5.0 years.

Regenesi s is still on the forefront of technology in the arena of oral GH. No other GH company can express this shelf life for their GH products with the science and testing to back it up. Most other companies selling oral GH have a shelf life of a maximum of 90 days and there is no GH left in the bottle.

For more information please contact us at the number below.

CLINICAL RESULTS OF "HGH"

To determine the effects of the HF-LD (high frequency/low dosage) method of growth hormone therapy, Dr. Edmund Chein and Dr. L. Cass Terry initially analyzed randomly selected questionnaires from 202 patients treated between 1994 and 1996. They ranged in age from 39 to 74 years old, with women making 15 percent of the study population. The exciting results of this study are shown in the table below labeled "Assessment."

According to Chein and Terry, 'The most outstanding results were improvements in muscle strength, exercise endurance, and loss of body fat. Also, there were significant improvements in skin, healing capacity, sexual drive and performance, energy level, emotions/attitude, and memory. There were also significant drops in cholesterol and

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triglycerides. In general, these improvements occurred within 1 to 3 months and continued to increase over 6 months.

Assessment

Effects of human growth hormone administration (high frequency, low dose)
202 patients

L. Cass Terry, MD, Ph.D., and Edmund Chein, MD

Medical College of Wisconsin and Palm Springs Life Extension Institute

Strength, Exercise, and Body Fat	Improvement
Muscle strength	88 percent
Muscle size	81 percent
Body fat loss	72 percent
Exercise tolerance	81 percent
Skin and Hair	
Skin Texture	71 percent
Skin Thickness	68 percent
Skin Elasticity	71 percent
Wrinkle Disappearance	61 percent
New Hair Growth	38 percent
Healing, Flexibility, and Resistance	
Healing of Old Injuries	55 percent
Healing of Other Injuries	61 percent
Healing Capacity	71 percent
Back Flexibility	83 percent
Resistance to Common Illnesses	73 percent
Sexual Function	
Sexual Potency/Frequency	75 percent
Duration of Penile Erection	62 percent
Frequency of Nighttime Urination	57 percent
Hot Flashes	58 percent
Menstrual Cycle Regulation	39 percent
Energy, Emotions, and Memory	
Energy Level	84 percent
Emotional Stability	67 percent
Attitude Toward Life	78 percent
Memory	62 percent

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REGENESIS GH AUTHENTICATION

ABCO Laboratories Inc.

December 15, 1999

ABCO Laboratories Inc. performs HGH testing using the Human Growth Hormone Advantage Chemiluminescence Assay by Nichols Institute Diagnostics. The instrument used to perform this testing is the Nichols Advantage Chemiluminescence System.

RIA-Endocrinology Study:

Source Chemical Assay Quantitative Results Regenes plus (30 ml)
Somatotropin (GH) 321.6 ng/spray 2010 ng/ml

Diluted and confirmed

PLS Laboratories - Vista, California

December 4, 2000

PLS Laboratories performs HGH testing using the Human Growth Hormone Advantage Chemiluminescence Assay by Nichols Institute Diagnostics. The instrument used to perform this testing is the Nichols Advantage Chemiluminescence System.

RIA-Endocrinology Study:

Source	Chemical Assay	Quantitative Results
Regenes Plus (30 ml)	Somatotropin (GH)	341.6 ng/spray 2050 ng/ml

Diluted and confirmed

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Unfolded Proteins Efficiently Penetrate Cell Membranes Implications for Oral Delivery Methods

Milstein SJ, Leipold H, Sarubbi D, Lrone-Bay A, Mlynek GM, Robinson JR, Kasimova M, Freire E. Partially unfolded proteins efficiently penetrate cell membranes-implications for oral drug delivery. *J Controlled Release* 1998 Apr. 30; 53 (1-3): 259-67

Emisphere Technologies, Inc., Hawthorne, NY 10532, USA
SMilstein@emisphere.com

We have previously reported on the biological activity of members of a library of low molecular weight compounds (carriers) that enable the oral delivery of proteins (Milstein, Proceedings of the 1995 Miami Bio/Technology Winter Symposium on Protein Engineering and Structural Biology, IRL Press at Oxford University Press, 1995, p. 13; Leone-Bay et al., *J. Med. Chem.* 38 (1995) 4263-4269; Leone-Bay et al., *J. Med. Chem.* 39 (1996) 2571-2578;[1-3]. When rats or primates are orally administered a solution of carrier and either recombinant human alpha-interferon (rhIFN), insulin or recombinant human growth hormone (rhGH) significant serum concentrations of the proteins are detectable. The transport activity of these compounds is positively correlated with their structural effects on the protein molecule. Direct measurement of the interaction of these carrier molecules with the proteins indicates that they reversibly destabilize the native state of the molecule favoring a partially unfolded conformation. Apparently these intermediate protein conformations are transport competent and are able to be absorbed through the intestinal tissue and into the bloodstream. Since the measured binding of the carriers to the partial unfolded proteins is relatively weak ($K_B = 100 \text{ M}^{-1}$) and systemic activity of the proteins appears to be unaffected, the changes in the structure of the proteins are manifestly reversible.

PMID: 9741933, UI: 98412964

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The New England Journal of Medicine

Volume 323

July 5, 1990

Number 1

EFFECTS OF HUMAN GROWTH HORMONE IN MEN OVER 60 YEARS OLD

Daniel Rudman, MD, Axel G. Feller, MD, Hoskote S. Nagraj, MD, Gregory A. Gergans, MD, Pardee Y. Lalitha, MD, Allen F. Goldberg, DDS, Robert A. Schlenker, Ph.D., Lester Cohn, MD, Inge W. Rudman, BS, and Dale E. Mattson, Ph.D.

Abstract Background. The declining activity of the growth hormone-insulin-like growth factor 1 (IGF-1) axis with advancing age may contribute to the decrease in lean body mass and the increase in mass of adipose tissue that occur with aging.

Methods. To test this hypothesis, we studied 21 healthy men from 61 to 81 years old who had plasma IGF-1 concentrations of less than 350 U per liter during a six-month baseline period and a six-month treatment period that followed. During the treatment period, 12 men (group 1) received approximately 0.03 mg of biosynthetic human growth hormone per kilogram of body weight subcutaneously three times a week, and 9 men (group 2) received no treatment. Plasma IGF-1 levels were measured monthly. At the end of each period, we measured lean body mass, the mass of adipose tissue, skin thickness (epidermis plus dermis), and bone density at nine skeletal sites.

Results. In group 1, the mean plasma IGF-1 level rose into the youthful range of 500 to 1500 U per liter during treatment, whereas in group 2 it remained below 350 U per liter. The administration of human growth hormone for six months in group 1 was accompanied by an 8.8 percent increase in lean body mass, a 14.4 percent decrease in adipose-tissue mass, and a 1.6 percent increase in average lumbar vertebral bone density (Proximal femur. In group 2 there was no significant change in lean body mass, the mass of adipose tissue, skin thickness, or bone density during treatment.

Conclusions. Diminished secretion of growth hormone is responsible in part for the decrease of lean body mass, the expansion of adipose-tissue mass, and the thinning of the skin that occurs in old age. (New England Journal of Medicine, 1990; 323:1-6).

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European Journal of Endocrinology 1994, 130: 224-8

Three years of growth hormone treatment in growth hormone-deficient adults: near normalization of body composition and physical performance

Jens OL Jørgenson¹, Leif Thuesen², Jørn Müller³, Per Ovesen¹, Niels E Skakkebæk³ and Jens S Christiansen¹

Medical Department M (Diabetes and Endocrinology), and Institute of Experimental Clinical Research¹, Aarhus Kommunehospital, Aarhus, Denmark; Department of Cardiology², Skejby Sygehus, Aarhus, Denmark; Institute of Growth and Reproduction³, Rigshospitalet, Copenhagen, Denmark

Jørgensen JOL, Thiesen L, Müller J, Ovesen P, Skakkebæk NE, Christiansen JS. Three years of growth hormone treatment in growth hormone-deficient adults: near normalization of body composition and physical performance. Eur J Endocrinol 1994;130:224-8. ISSN 0804-4643

Growth hormone (GH) replacement therapy in several controlled short-term trials have shown unanimous beneficial effects on body composition and other features. To evaluate more long-term effects we report data from 3 years of uninterrupted GH therapy in 10 different GH-deficient adults who had all months of open GH therapy. No further increase in linear height was observed. The initial increase in thigh muscle volume was recorded. Exercise capacity and isometric muscle strength were increased significantly compared to the initial placebo period. This was associated with stabilized levels of resting heart rate and blood pressure. Glycosylated hemoglobin levels were normal and did not change during the study. A standard oral glucose tolerance test performed at the end of the study revealed no evidence of glucose intolerance. No side-effects were reported. Compared to an age- and sex-matched group of healthy untreated subjects, thigh muscle volume, exercise capacity and isometric muscle strength had become normalized from subnormal levels after 3 years of GH therapy.

We conclude that long-term GH replacement therapy in GH-deficient adults is associated with preserved beneficial effects on body composition and physical performance, resulting in a near normalization of several previously abnormal features and adding new merits to this treatment modality.

Jens OL Jørgensen, Medical Department M (Endocrinology and Diabetes), Aarhus Kommunehospital, DK-8000C, Denmark

Within the last 4 years several studies on growth hormone (GH) treatment in GH-deficient adults have been published (1, 2). This in turn has prompted surveys on epidemiological and clinical features of hypopituitary adults (3-9). It has become evident that untreated GH deficiency in adulthood is associated with abnormal body composition in terms of increased fat mass (4, 5, 7, 9), decreased lean

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body mass (5, 8), decreased extra cellular water (5, 7, 9) and decreased bone mineral content (4, 6). In addition, there is suggestive evidence of a substantially increased mortality in these patients due to cardiovascular disease (3, 4). Growth hormone treatment in adult patients has shown unequivocal beneficial effects as regards part normalization of body composition (10-16). Furthermore, GH therapy has been shown to improve exercise capacity (10, 12, 14, 16, 17) and muscle strength (12, 18) from distinctly subnormal levels. Additional potentially beneficial effects of GH therapy on several other features also have been reported (10, 11, 13, 15, 19-24). So far, the only substantial side-effect has been subjective discomfort related to fluid retention, which in most instance is a transient dose-dependent occurrence. Still, the well-known insulin antagonistic actions of GH may cause concern.

The duration of GH therapy in presently published trials has not exceeded 16 months. Therefore, we have found it relevant to report in this paper the data on 3 years of uninterrupted GH therapy in GH-deficient adults.

QUESTIONS & ANSWERS

HOW MUCH GH DOES THE ORAL DIETARY SUPPLEMENT REGENESIS GH CONTAIN IN COMPARISON TO THE hGH INJECTIONS?

In the early 80's, Eli Lilly introduced the first viable rhGH product administered intramuscularly through daily injections. The hGH was manufactured using recombinant DNA technology. With the injections, the dosage varies, but a standard dose is between 1 and 4 I.U. (international units) per injection. Since most doctors prescribe 1/2 shot, 2 times per day, a given individual takes in between 1 and 4 I.U.'s per day. Regenesis Pro 500 has 500ng of GH per spray and there are approximately 350,000 nanograms per I.U. Most people take between 3 and 6 sprays per day or between 0.0043 and 0.0086 I.U. per day.

WHAT IS THE STANDARD DOSAGE FOR THE hGH INJECTIONS AND THE ORAL DIETARY SUPPLEMENT REGENESIS GH?

The hGH injections are administered by the patient subcutaneously in the leg between one and two times per day, five (5) days a week, or for three (3) straight weeks, laying off the product for the fourth (4th) week.

Regenesis GH should be administered as follows: one (1) spray, three (3) to eight (8) times a day, seven days per week. The maximum daily dosage is eight (8) sprays per day, seven days per week. Regenesis GH should be used just before retiring in the evening to allow its regenerative properties to work.

WHERE DOES THE GH IN REGENESIS GH COME FROM?

The growth hormone in Regenesis GH is not derived from any person or animal. It is derived from bacteria through a process known as "recombinant DNA." The gene of a bacterium is altered to produce human growth hormone, which is a small protein consisting of 191 amino acids, and it is harvested from the bacterial culture. Regenesis

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GH is identical to the growth hormone your body produces. Bacteria are used to synthesize other biochemical compounds including antibiotics, Vitamin B-12, and Coenzyme Q-10.

HOW LONG WILL IT TAKE TO SEE RESULTS WHEN USING REGENESIS GH,?

Some people notice improvements within a few weeks, such as increased energy, better sleep, and better mood. However for others it takes longer. **A trial period of at least a six month is recommended.** Structural improvements in skin and hair definitely take longer, months and not weeks. Remember that the initial benefits occur "on the inside" before eventually manifesting "on the outside". If you practice a healthy lifestyle while using Regenesi s GH, you are likely to see results faster.

HOW CAN I BE SURE THAT REGENESIS GH IS SAFE?

The dosage of Recombinant GH in Regenesi s GH, although high by oral standards, is still low by medical standards: much lower than is usually given by injection, and too low to have any adverse side effects. Yet this small safe dose works gently to stimulate the pituitary gland through a process known as "positive feedback."

WILL REGENESIS GH MAKE MY PITUITARY GLAND LAZY?

We see no evidence that Regenesi s GH inhibits pituitary activity; on the contrary it appears to strengthen it. No dependency is created from using Regenesi s GH, and there is no letdown or withdrawal syndrome if you were to suddenly stop taking it. Unlike other GH products, it is not necessary to cycle on and off with Regenesi s GH.

IS THE USE OF REGENESIS GH AFFECTED BY EATING?

Besides the obvious effect that if you eat or drink something shortly after using it you are going to wash it down before it can be absorbed, be aware that growth hormone works best in a low sugar, low insulin environment. Therefore, it would be best if you were to wait 20 minutes after you spray in the morning before eating breakfast. And likewise, it would be best if you wait at least 2½ hours after finishing eating before you spray.

WHAT IS THE DIFFERENCE BETWEEN THE hGH INJECTIONS AND THE ORAL DIETARY SUPPLEMENT REGENESIS GH IN TERMS OF DRUG STATUS?

Since the passage of the Food, Drug, and Cosmetic Act, Congress passed the Dietary Supplement Health and Education Act (DSHEA - 1994). DSHEA created a new food category for dietary supplements. In order for the FDA to remove a dietary supplement from the market, it must prove that the product causes undue harm to consumers.

DSHEA allows for low dose hormones (e.g. oral hGH, DHEA, melatonin, phytoestrogen, wild yam cream, natural testosterone, etc.) to be sold and marketed as dietary

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supplements. When delivered using a safe method of administration (e.g. a tablet, capsule, cream, sublingual, etc.), hormones fall into the category of foods, not drugs.

In addition, when the rhGH molecule is stabilized by additional amino acids and wrapped in a lipid (often called a polymer matrix), it is no longer hGH but the oral dietary supplement GH.

Therefore, under the DSHEA of 1994, low dosage, orally administered GH is marketable without a prescription.

DOES REGENESIS GH NEED TO BE REFRIGERATED?

Regenesi GH has a shelf life of two years (*page 26*) and does not require refrigeration. The GH found in Regenesi GH is stabilized by the polymer matrix, eliminating the need for refrigeration. However, the product should be kept between 1°C (33°F) and 49°C (120°F) and out of direct sunlight.

WHAT IS THE DIFFERENCE BETWEEN HGH AND IGF-1?

HGH is the master hormone of the body. HGH is produced by the master gland, the pituitary. HGH regulates the production of IGF-1, or insulin-like growth factor-1, a liver hormone responsible for albumin production.

IGF-1 is in the same metabolic pathway as HGH. Research has shown that raising HGH levels increases IGF-1 levels 60% of the time, maintains IGF-1 levels 20% of the time, and decreases them 20% of the time. **After a period of 3 to 9 months most patients will show a drop in circulating serum IGF-1 as the number of receptor sites increases.**



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