

BAYWOOD RESEARCH MODULE

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Dr. Harris' Original SNORE formula

A Natural Dietary Supplement for the Relief of Snoring

ETIOLOGY

Snoring is caused by the nightly accumulation of respiratory secretions that produce a partial obstruction to airflow toward the back of the throat. This partial obstruction produces a disturbance in the airflow pattern, resulting in vibration of the soft tissues in the back of the throat that produces the snoring sound. Our respiratory system constantly produces secretions in the nasal cavity, sinuses, bronchi and lungs. Although we easily dispose of these secretions during the day, the secretions begin to accumulate in the back of the throat at night when we lie down in the horizontal position. These secretions begin to irritate the surrounding tissues, producing congestion and swelling. These factors produce a partial obstruction to the airflow, resulting in airflow turbulence which vibrates the soft tissues in the back of the throat and produces the sound of snoring. The narrowing of the airway due to the tissue swelling causes snoring to occur more easily. More than eighty-five percent (85%) of the cases of snoring are due to these factors.

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Physiologic factors that can aggravate snoring include conditions that increase the production of respiratory secretions such as respiratory allergies, chronic sinusitis, post-nasal drip, cigarette smoking and late-night snacks. Excess alcohol intake prior to bedtime loosens the soft tissues and allows snoring to occur.

Any structural abnormalities which decrease the available airway space make it easier for the partial obstruction to occur and are, therefore, aggravating factors in snoring. These include enlarged tonsils and adenoids in children, an enlarged and loose tongue, malformations or posterior shifting of the mandible (lower jaw), swollen or elongated uvula, obesity (which narrows the airway), deviation of the nasal septum and/or nasal polyps.

WHAT MAKES SNORING WORSE?

There are many factors that have been identified which may increase the frequency and/or severity of snoring. These include the following:

(1) **Obesity.** Excess weight gain results in the deposition of fat in all tissues, including those around the throat and airway. This produces narrowing of the airway, loosening of the soft tissues and allows snoring to occur more easily.

(2) **Alcohol Consumption at Night.** Consuming the equivalent of more than two (2) drinks through the evening results in excess relaxation of the soft tissues in the back of the throat. These tissues then vibrate more easily, producing more frequent and more severe snoring.

(3) **Increased Respiratory Secretions.** This condition may arise because of many factors, including cigarette smoking, chronic bronchitis, allergies, chronic sinusitis, chronic rhinitis (nasal congestion) and mucous-producing foods eaten in the evening, such as dairy products.

WHY SHOULD SNORING BE A CONCERN?

Although snoring has been the object of jokes and cartoons, medical science has determined that snoring is associated with serious medical conditions.

Medical Problems Relating to Snoring

Snorers are known to have a much higher rate of heart attacks, strokes and high blood pressure than non-snorers. The risk of developing these medical problems increases the longer that a person snores and the more severely they snore. The arterial oxygen saturation levels in the majority of snorers have been found to be below normal resulting in repetitive episodes of hypoxia to the brain and other vital organs. Long-term studies have demonstrated that snorers have a 400% to 500% higher risk of developing heart attacks, strokes or hypertension.⁶⁻¹⁰ Since snoring is always progressive, it will lead to sleep apnea in over thirty percent (30%) of all adults and in over fifty percent (50%) of all children if uncontrolled.^{11, 12, 13}

Additionally, the sleep pattern of snorers is extremely abnormal, exhibiting up to sixteen (16) micro arousals per hour. This combination of events leads to daytime fatigue, shorter attention span, slower reflexes and difficulty in concentration.^{2, 3} It has recently been shown that this type of poor sleep pattern results in decreased production of human growth hormone in middle-aged males, leading to decreased energy, obesity, reduced libido and reduced sexual performance.

In addition, studies done at Stanford University and other institutions have shown that snorers have a higher rate of automobile accidents than non-snorers. Snoring is known to cause reduced oxygen flow to the brain and other organs, resulting in daytime fatigue or sleepiness, slower reflexes and reduced attention span. These factors cause impairment of our ability to concentrate on road and traffic conditions. Many studies have shown that snorers have a 300% to 400% higher risk of being involved in an automobile accident compared to non-snorers, and a 700% higher risk of being involved in multiple automobile accidents compared to non-snorers.^{4, 5}

Therefore, it is critical that snoring be brought under control and kept under control indefinitely. By keeping the snoring under control, the risk factors for all these serious medical conditions gradually decrease over a period of years.

Social Consequences of Snoring

Snoring is often a significant factor in relationships, causing disturbed sleep patterns, daytime fatigue and hyper-irritability in the non-snorings partner. In more extreme cases, the partners have to sleep in separate bedrooms. The constant exposure of the snorer's mate to "second hand snoring" results in poor sleep patterns for that individual, a predisposition to hyperirritability, anger, anxiety, and depression. Eventual separation of the parties at night leads to a reduction in intimacy. Many studies have shown that snoring is a major factor in the dissolution of relationships and divorces. This produces increasing resentment, loss of intimacy and, eventually, deterioration of the relationship. These factors also cause anxiety and depression, often leading to failing relationships with friends and co-workers, as well as reduced work performance.

WHO SNORES?

Medical authorities have estimated that up to forty percent (40%) of the entire population are chronic, regular snorers and twenty-five percent (25%) of all pre-adolescent children are regular, chronic snorers.¹ This problem affects more than 100,000,000 people in the United States with similar statistics emerging in other countries around the world. Although snoring is found predominantly in men, forty percent (40%) of all snorers are women.

Snoring also increases in severity and prevalence with increasing age. For example, an average 20 year-old group would include five percent (5%) of females and twenty-nine

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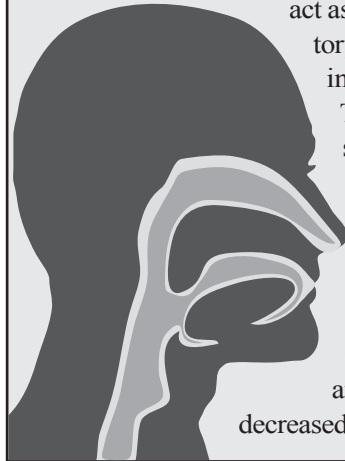
percent (29%) of males that are chronic snorers, an average 50 year-old group would include forty percent (40%) of females and sixty percent (60%) of males that are chronic snorers, and an average 70 year-old group would include seventy percent (70%) of all males and females that are chronic snorers.

DR. HARRIS' ORIGINAL SNORE FORMULA™

This unique formulation includes a patented combination of 100% natural enzymes and herbs formulated and tested specifically for snoring. The product contains a proprietary blend of four plant derived digestive enzymes (Amylase, Cellulase, Lipase and Protease) along with eleven herbs. The herbs include Acerola Concentrate (fruit), Cayenne (fruit), Echinacea (root/aerial part), Rose Hips (fruit), Fenugreek (seed), Slippery Elm (bark), Red Clover (aerial part), Yarrow (flower), Yellow Dock (root), Eucalyptus (leaf) and Elderberry (flower/fruit). These compounds are repeatedly tested to insure the highest quality and potency.

Mechanism of Action:

When taken on an empty stomach, the caplets are formulated to disintegrate and be absorbed in ten (10) to twelve (12) minutes. The enzymes act to break-down and digest the mucous secretions, allowing the body to metabolize and absorb them. They also act as a natural anti-inflammatory,



decreasing any tissue inflammation and swelling.

The herbs also reduce the secretions, alleviate tissue congestion, and decrease the production of additional secretions.

The result is that the airway is opened, the air-flow is smoothed out and the snoring is markedly decreased or eliminated.

How Should Dr. Harris' Original Snore Formula™ be Taken?

To derive the maximum benefits from the product, it must be taken correctly. The dosage is initially determined by weight. If the subject's weight is 125 lbs or less, the suggested dose is one (1) to two (2) caplets, 125 to 220 lbs the suggested dose is two (2) to three (3) caplets, and over 220 lbs the suggested dose is three (3) to four (4) caplets. The product should always be taken on an empty stomach.

Every individual is unique, and therefore the dosage will vary considerably. To obtain the fastest and best results, it is highly recommended to double the usual starting dosage for the first week. After the maximum benefit is obtained, this dosage may be lowered by one-half (1/2) caplet each week until the lowest dose that controls snoring is achieved. This lowest dose should be continued as the maintenance dosage indefinitely.

Higher dosages may produce some dryness in the nose and throat. This only indicates that the product is working. A humidifier will relieve the dryness if it continues to be a concern.

There are many things that can be done to increase the effectiveness of the product, including the following:

- (1) Take the product thirty (30) to forty-five (45) minutes before bedtime.
- (2) Be sure to take the product on an empty stomach. Do not eat for two hours before taking the product.
- (3) Avoid dairy products such as milk, butter, cheese, etc. for four hours before bedtime, as they may increase the production of respiratory secretions.
- (4) Severe allergies, smoking, alcohol consumption and bedtime snacks tend to make snoring worse. These conditions may require an increased dose of the product by one-half (1/2) to one (1) caplet in order to obtain satisfactory results.

Lifestyle changes, including weight loss, stopping cigarette smoking, reducing evening alcohol consumption and snacking will not only improve snoring control but will also lead to better health.

How Safe Is Dr. Harris' Original Snore Formula™?

Since the product is a 100% natural formulation, no side effects and allergic reactions commonly associated with over the counter and prescription medications have been reported. In fact, after two years of clinical studies and thousands of satisfied users, there have been no reports of side effects, allergies or intolerance of the product. Furthermore, many of the people now using the product are taking other medications as well. To date, no reports of cross-reactions with any other medication have been reported. It is recommended that pregnant or nursing mothers consult their physician prior to taking this product.

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Can I Give Dr. Harris' Original Snore Formula™ To My Child?

Since children's tonsils and adenoids are no longer routinely removed, it is estimated that twenty percent (20%) to twenty-five (25%) of all adolescent children are now chronic snorers. Many of these children also suffer from sleep apnea, a condition in which the person completely stops breathing for up to thirty (30) seconds or more each hour. This is a serious medical condition in which a physician should be consulted. The product is being taken by hundreds of children and there have been no reports of side-effects or adverse reactions.

The recommended dosage for children weighing 65 to 125 lbs is one (1) caplet and for those weighing less than 65 lbs, one-half (1/2) caplet. Parents should check with their physician before giving the product to children younger than six (6) years of age.

HOW EFFECTIVE IS DR. HARRIS' ORIGINAL SNORE FORMULA™?

- Two years of clinical testing by Dennis Harris, M.D. on 220 chronic snorers produced good to excellent results in eighty-six percent (86%) of the test subjects taking this formulation.
- Good Housekeeping, in an independent study, demonstrated that the formulation used in *Dr. Harris' Original Snore Formula™* produced major improvement in the vast majority of test subjects.
- Reports from the over 100,000 regular users of the product indicate a similar level of satisfaction.

DOES DR. HARRIS' ORIGINAL SNORE FORMULA™ HAVE TO BE TAKEN FOREVER?

Like many medical problems, such as heart disease, hypertension and diabetes, snoring is a condition that can be controlled, but not cured. Therefore, once a maintenance dosage level has been determined, the product must be taken regularly and indefinitely.

Many users of *Dr. Harris' Original Snore Formula™*, after maintaining good results for five (5) to six (6) months, are able to gradually reduce their dosage even further.

It is vitally important that snoring is kept under control indefinitely. The longer snoring is controlled, the lower the risk factors for heart attacks, strokes and high blood pressure.

ARE THERE ANY OTHER BENEFITS OF DR. HARRIS' ORIGINAL SNORE FORMULA™?

The top quality herbs and enzymes used in *Dr. Harris' Original Snore Formula™* have many other significant benefits. Recent studies suggest that protease may actually help maintain healthy cholesterol and circulation levels. Protease,

lipase and amylase work together to help relieve heartburn and gastric irritation, improving digestion and improving the absorption of the herbs contained in the formula.

The herbs used in this formulation have long been recognized as providing significant health benefits including anti-oxidant activity, stimulation and maintenance of the immune system, improved digestion, cleansing of toxins from the blood, antiviral activity, antibacterial activity, anti-inflammatory activity, decrease in serum cholesterol and triglycerides and reduction of LDL cholesterol.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR SNORING?

Many attempts to treat snoring have been made through the years without much success. From the standpoint of medications, antihistamines, sedatives, anti-inflammatories, anti-depressives and anti-anxiety preparations have been notably unsuccessful in controlling the problem. In addition, various types and shapes of pillows have been tried with little success as well as homeopathic medications which have had a very poor record of success. Dental appliances that shift the lower jaw forward or pull and hold the tongue forward have only met with limited success.

A number of products are offered for snoring, some of which include oil-based sprays. The American Academy of Sleep Disorders cautions against the use of these sprays. While the oil-based sprays lubricate the tissues allowing air to flow more freely, they also create a "heavy tissue." The weight of the oil on the tissue surface helps to prohibit vibration that is the cause of the snoring sound. When a spray is applied to the back of the throat, some of the oil enters the gastrointestinal tract and is excreted. However, the danger occurs because some of the oil enters the lungs and is not excreted. It collects in pools in the lungs and may lead to a serious condition known as "Lipoid Pneumonia". There is no treatment for this other than surgery to remove the oil.

Finally, the newer surgical procedures using conventional or laser surgery that remove large amounts of tissue from the back of the mouth have proven far less than ideal. They cause pain which may linger for up to three (3) months following surgery. Several deaths have now been reported as directly resulting from the procedure. Many complications have also been reported, including the development of nasal speech, difficulty in swallowing, change in taste sensation and nasal regurgitation which occurs when food or liquid that you intend to swallow goes up instead of down and exits through the nose due to the removal of large amounts of tissue. The worst problem, however, is that not only does surgery almost never completely eliminate snoring, but when patients having had these surgical procedures are evaluated thirteen (13) months afterward, only forty-six percent (46%) even obtained a minimal decrease in snoring.

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SAFETY AND EFFICACY STUDIES

Empirical Observations

Since 1995, the product has been used by over 200,000 people with good to excellent results having been achieved in over eighty-five (85%) of users with no reports of side effects, allergic reactions or medication interactions. The user group includes all ages from infancy to patients in their 90's who are taking a large variety of medications for all types of medical conditions.

Adverse Effects & Toxicity

Product Safety Labs in East Brunswick, New Jersey performed an acute oral toxicity study in rats from March 27, 2000 through April 04, 2000. Ten (10) rats were given 5,000mg/kg of the product in suspension. After fourteen (14) days of daily observation, no changes in weight, activity, behavior or eating patterns were observed. No signs of gross toxicity or adverse pharmacologic effects were noted. Post-mortem examinations were totally normal.

Clinical Tests:

In order to adequately test the product and derive the most effective formulation, eleven different compositions of the product were made. Each composition was separately tested on twenty subjects. Effectiveness was reported by the test subject and/or their family.

The formulation was given to each test subject by weight in the following manner: 125lbs or less, one (1) tablet; 125lbs to 220lbs, two (2) tablets; and over 220lbs, three (3) tablets. The product was administered thirty (30) to forty-five (45) minutes prior to bedtime in all cases.

RESULTS WERE GRADED IN THE FOLLOWING MANNER:

Poor: 0% to 49% improvement

Good: 50% to 74% improvement

Excellent: 75% to 100% improvement

TESTING:

Group I:

6 females, 14 males
Ages 24 - 67 years.
Weight 102lbs - 205lbs

Results:

Poor 30%.
Good 55%.
Excellent 15%.

Group II:

4 females, 16 males,
Ages 18 - 56 years.
Weight 98lbs - 240lbs

Results:

Poor 15%.
Good 30%.
Excellent 55%.

Group III:

9 females, 11 males.
Ages 18 - 76 years.
Weight 113lbs - 209lbs

Results:

Poor 10%.
Good 35%.
Excellent 55%.

Group IV:

10 females, 10 males.
Ages 23 - 62 years.
Weight 106lbs - 232lbs

Results:

Poor 15%.
Good 30%.
Excellent 55%.

Group V:

12 females, 8 males.
Ages 21 - 58 years.
Weight 122lbs - 196lbs

Results:

Poor 25%.
Good 60%.
Excellent 15%.

Group VI:

9 females, 11 males.
Ages 20-60 years.
Weight 110lbs - 265lbs

Results:

Poor 25%.
Good 65%.
Excellent 10%.

Group VII:

13 females, 7 males.
Ages 18-72 years.
Weight 94lbs - 202lbs

Results:

Poor 25%.
Good 60%.
Excellent 15%.

Group VIII:

5 females, 15 males.
Ages 26-69 years.
Weight 101lbs - 214lbs

Results:

Poor 30%.
Good 55%.
Excellent 15%.

Group IX:

9 females, 11 males.
Ages 18-70 years.
Weight 102lbs - 202lbs

Results:

Poor 30%.
Good 50%.
Excellent 20%.

Group X:

10 females, 10 males.
Ages 18-67 years.
Weight 110lbs - 220lbs

Results:

Poor 20%.
Good 60%.
Excellent 25%.

Group XI:

8 females, 12 males.
Ages 22-65 years.
Weight 116lbs - 226lbs

Results:

Poor 15%.
Good 30%.
Excellent 55%.

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Clinical Tests (continued):

RESULTS:

The results for all formulations were averaged as follows:

Poor: 21.72%	Good: 47.96%
Excellent: 30.32%	Total: 100.00%

The results of all formulations containing the ingredient levels of Groups II, III, IV and XI were averaged as follows:

Poor: 13.75%	Good: 31.25%
Excellent: 55.00%	Total: 100.00%

The results of all formulations containing the ingredient levels of Groups I, V, VI, VII, IX and X were averaged as follows:

Poor	26.24%	Good	57.45%
Excellent	16.31%	Total	100%

CONCLUSIONS:

The same test subjects participated in more than one group in many cases. Studies included 220 test subjects and were performed over a two-year period.

It is significant that during the entire test period, not even one incident of side effects, allergy or intolerance to the product was encountered. Many of the test subjects were also taking a variety of medications for other medical conditions while testing the formula used in Dr. Harris' Original Snore Formula. No cross reactions to medications were reported.

The following conclusions were derived from the studies:

(1) The most effective formulations contain dosages of each ingredient equal to or in excess of the formulations used in Groups II, III, IV and XI, yielding good to excellent results in 86.25% of test subjects.

(2) The product is effective equally in either sex or at any age.

(3) The product was effective in test subjects of any weight as long as the dosage schedule was observed.

(4) The product was felt to be extremely safe for adults of any age, sex, or weight.

QUALITY CONTROL

All raw ingredients are tested immediately upon receipt. Test results are compared with the raw material supplier's Certificate of Analysis (C of A). If the results are not within five percent (5%) of the C of A, the batch is returned. Manufacturing is accomplished using strict Good Manufacturing Practices (GMP) standards in a state-of-the-art facility. Quality control checks are performed at nine additional stages in the manufacturing procedure. Final product testing is performed prior to product release.

Shelf-Life

Real time shelf-life testing in normal room conditions was carried out on this product. No degradation of the product could be detected after three (3) years.

Storage

Store in a dry, cool place. Avoid excessive heat and protect from light.

How Supplied

Dr. Harris' Original Snore Formula™ is supplied in a 60 Count bottle and 6 Count Trial Pack. The coated caplets are USP quality and are formulated to dissolve in ten (10) to twelve (12) minutes after ingestion.

Warning

Pregnant or nursing females should consult a healthcare professional before taking this product.

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Directions for Use:

For maximum benefit, the product should be taken on an empty stomach thirty (30) to forty-five (45) minutes before bedtime according to the following schedule:

65 lbs or less: 1/2 - 1 caplet

65 lbs to 125 lbs: 1 - 2 caplets

125 lbs to 220 lbs: 2 - 3 caplets

220 lbs or more: 3 - 4 caplets

Note: Taking this product with food in the stomach will significantly reduce the anticipated benefits. If the product is taken on a full stomach, a higher dose will be required to achieve the desired effect. For faster results, double the recommended dosage for two to three weeks, then decrease the nightly dosage by one-half (1/2) caplet per week to find the lowest effective dosage level.

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MISSION:

At Baywood, we are ardent advocates for advancing the quality of life. Our goal of "Making Life Better"™ is based around understanding that everyone is unique as individuals so that we can develop nutraceuticals of the highest quality while providing the highest accessibility amongst all consumer channels.

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OUR COMMITMENT TO CHANGE:

At Baywood, we are actively involved in the trends that affect our consumers. As the nutraceutical industry continues to advance, we strive to refine our competitive edge by refining the products we offer to the marketplace. We achieve this objective by identifying new scientific advancements for the ingredients we use and quickly modifying product formulations to changing consumer needs and demands. We ask that you expect this change within our product formulations as you grow with us as a customer. From time-to-time, you might see improvements in products that you already purchase from us. This is our commitment to you as our customer. This is our commitment to change. This is our commitment to "Making LIFE Better".

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