

# I N N A T E

RESPONSE FORMULAS<sup>®</sup>

## Cholesterol Response<sup>™</sup>

V i s m e d i c a t r i x n a t u r a e

### Product Rationale

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# Cholesterol Response™

## Innate Response Formulas™ Rationale

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When crafting all Innate Response Formulas®, our mission is to harness the innate healing response that is within every patient in the time honored traditions of "vis medicatrix naturae". Following this time honored tradition we will only use the nutrient- finest rich whole foods and botanicals that are aligned with these principals.

Cholesterol Response™ was designed to provide comprehensive nutritional support for cholesterol management through LDL reduction, enhanced HDL production, inflammation reduction, immune function and protection against lipid oxidation\*\*.

Current research suggests that the biochemical processes related to cholesterol and its contribution to heart attacks, strokes, and Atherosclerosis can be reversed or modulated with dietary intervention that includes select foods particularly rich in fiber and antioxidant compounds. Cholesterol Response™ was crafted from select whole foods and botanicals that have been used traditionally and researched to maintain healthy cholesterol levels and support cardiovascular health.

Contraindications: Do not use this formula during pregnancy, lactation or if patient is planning parenthood. Do not use this supplement with prescription or OTC cholesterol-lowering drugs without consulting with your health care provider and/or pharmacist as this supplement may enhance their actions and/or effectiveness. Do not use two weeks prior to or after surgery.

### Overview of Cholesterol Strength™ Cholesterol Management Formula

*“Contrary to public perception, the heart attacks and strokes that result from atherosclerosis exceed cancer as a cause of death in industrialized nations and are growing more prevalent in developing countries as well” [1].*

Hypercholesterolemia with elevated Low Density Lipoprotein (LDL) cholesterol is a recognized factor for Coronary Heart Disease (CHD). CHD is the leading cause of death in the United States. With an estimated 36 million Americans at risk for heart attack or stroke due to elevated blood lipid levels, cholesterol management has become a concern for many of the adult population. High LDL levels cause oxidative stress in the cardiovascular system contributing to the development of atherosclerotic plaque, a primary cause of CHD. Diet and lifestyle choices can be significant contributing factors in CHD, life expectancy and general well being.

An enlightening article appeared in *Scientific American* [1] where researchers reveal that atherosclerosis is more than a “straight plumbing problem” created by fat-laden gunk gradually building up on passive arterial walls. Researchers have discovered that inflammation and resultant immune response mechanisms play a key role in atherosclerosis; underlying the creation of plaque growth and rupture.

### Cholesterol

Cholesterol is a fat-like alcohol that travels through the bloodstream transported by High Density and Low Density Lipoproteins. High blood cholesterol levels in excess of 200 mg/dl are considered unsafe, although some experts now cite 180 mg/dl as the maximum healthy level (see chart 1).

The typical American diet, with a foundation of animal food, provides between 300-500 mg of cholesterol daily in the form of eggs, organ meats, beef, pork, shrimp and other sources of saturated fat. The liver works to balance cholesterol levels, even without the consumption of animal products. The liver synthesizes the cholesterol needed by the body, about 2000 mg per day, to be used in hormone production, lipid metabolism and cell growth and repair.

The National Institute of Health (NIH) conducted a seven year study on cardiovascular disease. They revealed that there exists a direct correlation between the reduction of serum cholesterol levels and the risk of heart disease. (ref. NIH Publication No. 01-3290 May 2001)

## **Prescription Solutions to High Cholesterol**

Statin drug prescriptions are on the rise. at a cost ranging from \$60.00 to \$120.00 per month. According to Robert Rountree, M.D., “Statins clearly have a downside’. Cerivastatin, marketed under the brand name Baycol™, was permanently taken off pharmacy shelves in 2001. It was removed after numerous reports of toxicity and thirty-one fatalities. Side effects of statins include inflammation of the muscles, liver problems, rashes, upset stomach, abdominal pain, constipation, diarrhea, and flatulence.

Statins work by blocking the enzyme that makes cholesterol in the liver” [21]. This enzyme is necessary for the production of Coenzyme Q10, an antioxidant essential for proper functioning of the heart and brain. Therefore one of the dangerous aspects of statins is a decrease in CoQ10 levels, the long-term affects of which are as yet unknown. Health experts believe this deficiency in CoQ10 could cause chronic fatigue, heart damage, congestive heart failure and neurodegenerative disorders.

Another side effect of Statin drugs is called polyneuropathy; a type of nerve damage that can cause pain, loss of feeling, tingling and weakness. Though the chance of this is small, this nerve damage can be long lasting or even permanent.

Using the wisdom gleaned from past experience, antibiotics and many other drugs demonstrate side effects when used over extended periods of time.

The cost of using statins is \$60.00 to \$120.00 per month.

## **Formula Facts**

In research and development of the Cholesterol Response™ formula we looked at cholesterol management, the cardio vascular system, the immune system and the liver. The Innate Response from nutrients found in both traditional and recent science is the basis for this formula.

The important physiological functions supported by the Cholesterol Response™ formula:

- Lowering of Low Density Lipoproteins (LDL), cholesterol and triglycerides
- Supporting healthy High Density Lipoproteins (HDL) levels in the blood
- Reducing and inhibiting LDL oxidation
- Management of cardiovascular inflammation
- Protection the cardiovascular system’s cells and collagen from free radical damage
- Supporting and protecting the liver
- Supporting general cardiovascular health

- Supporting the reduction of arterial plaque
- General antioxidant protection
- Lowering of Homocysteine levels
- Assisting the body's natural removal of excess cholesterol, triglycerides and other harmful lipoproteins from the body

**Diet and lifestyle adjustments are an important part of any cardiovascular health program.**

Cholesterol Response™ Formulation

## **FOODSTATE™ NUTRIENTS**

### **Citrus Bioflavonoid Complex**

*The Journal of Medicinal Food* published a study in 2001 researching the health benefits of citrus-based FoodState™ bioflavonoids and vitamin C on Hypercholesterolemic human subjects. Results indicated lowering of triglycerides by 16% [2].

Flavonoids are known for their hydrogen-donating antioxidant activity and free radical scavenging properties with transitional metal cations. Research indicates that flavonoid antioxidant activity plays an important role in inhibiting lipid peroxidation, LDL oxidation and scavenging oxygen radicals [11, 12, 14].

Citrus Bioflavonoids support the stabilization of cell membranes, including those of the vascular system.

Originally called Vitamin P, flavonoids were first discovered in the early 1800's. Extensive research has been done, especially over the last 20 years, demonstrating that flavonoids provide tremendous health supportive benefits.

**We have included the FoodState™ form of bioflavonoids for maximum efficacy. FoodState™ flavonoids have the naturally occurring BioActive Peptides necessary for optimal utilization.**

**Actions:** Antioxidant, antimutagenic, anticarcinogenic, antiviral and oestrogenic. Actions that benefit the physiology include: antioxidant protection, capillary and vascular support, supporting overall cardiovascular health, membrane stabilization, modulation of inflammatory processes, cancer prevention and treatment. Provides anti microbial action that helps protect cardiac tissue.

## **CARDIO NUTRIENTS AND CONCENTRATED FOOD**

### **Policosanols and Cholesterol**

Policosanols are a group of long-chain, aliphatic (non-ring) alcohols found in natural waxes in such plants as sugar cane, beeswax, rice bran, broccoli, spinach, oats and alfalfa. These constituents are important to the growth of plants and they act as a barrier for water.

In 1972 research into the cholesterol-lowering properties of Policosanol began with Japanese researcher Dr. Hiroko Sho. Dr. Sho identified that the wax and fatty alcohols from sugar cane rind as the active components in sugar cane. He revealed that these materials lower intra-hepatic and serum cholesterol levels.

There have been several double-blind, placebo-controlled human clinical studies demonstrating the effectiveness of Policosanol in reducing total cholesterol. In a 20-month study comprised of hyperlipidemic subjects taking 10 mg. daily (5 mg. twice daily) total cholesterol was reduced by 10%, LDL cholesterol was lowered by 11% and triglycerides by 18%. Non-Insulin Dependent Diabetics (NIDDM) with hypercholesterolemia consuming 10 mg daily had a reduction by 28.8% of total cholesterol, 44 % reduction in LDL cholesterol and an increase in beneficial HDL cholesterol by 23.5%.

There is another study, published in 2001, on subjects with hypocholesteremics caused by NIDDM, taking 20 mg of Policosanol daily. Results showed a reduction by 15.6 % of total cholesterol, 27.4% reduction in LDL cholesterol and an increase in HDL cholesterol by 17.6%. The same study revealed that doses higher than 20 mg. daily do not offer greater benefits.

The *American Heart Journal* published a study on Policosanols in February of 2002. They found that at doses of 10-20 mg. per day, Policosanol lowers total cholesterol by 17%-21% and LDL cholesterol by 21%- 29% and raises HDL's by 8%-15%. Daily does of 10 mg of Policosanol have been shown to be equally as effective as equal doses of simvastatin or pravastatin [56].

**Policosanols provides vascular protection.**

Policosanols combats and helps protect against atherosclerosis also by providing significant protection against the oxidation of LDL cholesterol. Oxidation of LDL creates a reaction that stimulates macrophage activity, causing them to become foam cells that penetrate the arterial walls. The results are inflammation, atherosclerotic lesions and the initiation of arterial obstruction.

Policosanols provides other cardiovascular benefits, reducing risk factors of Cardiovascular Disease (CVD):

Decreasing LDL oxidation, platelet aggregation, endothelial damage and smooth muscle proliferation [55]. Evidence suggests that the mechanism of action may be inhibition of hepatic cholesterol synthesis at a step before mevalonate generation. Studies also suggest that LDL catabolism may be enhanced through receptor-mediated mechanisms, but the exact method of actions is not totally understood [56].

Research indicates Policosanol demonstrates long-term usefulness in treatment of intermittent claudication, a limping condition caused by ischemia (obstruction of blood supply) of the muscles [57].

Further research into Policosanol's affects on the nerves, nerve regeneration and brain functions are underway, and initial results are very promising.

**Sugar Cane and Rice Bran for a broad spectrum of Policosanols.**

Research indicates that the combined actions of a broad spectrum of aliphatic alcohols is superior to an isolated aliphatic alcohol. Identified Policosanols include: Octacosanol, Docosanol, Tetracosanol, Hexacosanol, Heptacosanol, Nonacosanol, Triacontanol, Dotriacontanol, Tetratriacontanol, Hexatriacontanol.

<b>C'S</b>	<b>ALIPHATIC</b>	<b>SUGARCANE</b>	<b>BENEDOSANOL™</b>
22	Docosanol	<b>0%</b>	<b>0-2%</b>
24	Tetracosanol	<b>4%</b>	<b>5-10%</b>
26	Hexacosanol	<b>8%</b>	<b>7-20%</b>
27	Heptacosanol	<b>3%</b>	<b>&lt;1%</b>
28	Octacosanol	<b>64%</b>	<b>50-60%</b>
29	Nonacosanol	<b>2%</b>	<b>&lt;1%</b>
30	Triacontanol	<b>13%</b>	<b>20-25%</b>
32	Dotriacontanol	<b>5%</b>	<b>8-10%</b>
34	Tetratriacontanol	<b>2%</b>	<b>&lt;1%</b>
36	Hexatriacontanol	<b>0%</b>	<b>&lt;1%</b>

Octacosanol is a 28-carbon aliphatic alcohol is found in Sugar cane wax at 60-70% and Rice Bran Wax at around 17.5%. The most widely known of the policosanols.

- Docosanol is a 22-carbon aliphatic alcohol found in Rice Bran Wax at 6% and only trace amounts in sugar cane wax (Also found in *Pygeum africanum*).
- Triacontanol is a 30-carbon aliphatic alcohol. Sugar cane wax at 10-15% and Rice Bran Wax at 26%.
- Hexacosanol is a 26-carbon aliphatic alcohol. (Research suggests that it may enhance sciatic nerve regeneration.)

### **Policosanol has been Favorably Compared to several Hypercholesterolemic drugs.**

Policosanol has performed equal to or better than lovastatin, probucol, pravastatin, simvastatin and acipimox in type II hypercholesterolemia with fewer side effects [55].

### **Pomegranate Concentrate (*Punica granatum L.*):**

Historically the juicy, nutrient-rich Pomegranate was a useful fruit as it traveled well even in desert heat and has been consumed for hundreds of years. This beautiful red fruit has been written of in Greek mythology involving Demeter, the goddess of the grains and the harvest.

#### **Pomegranate juice has demonstrated antioxidant activity against LDL cholesterol.**

Research indicates that the Polyphenols in pomegranate protect Low Density Lipoproteins from oxidation, which can lead to arteriosclerosis, heart attack, stroke and possibly Alzheimers and dementia.

Pomegranate is rich in antioxidants that are associated with “inhibition of atherogenic modifications to LDL, macrophage foam cell formation and atherosclerosis” [3]. Pomegranate juice also reduced platelet aggregation in the same study.

### **Recent Studies on Pomegranate Preventing Arterial Plaque Formation**

A human study in Israel found that Pomegranate juice reduced oxidation of LDL cholesterol by 43%. This study also found that atherosclerotic lesions shrank by 44 percent. The research expert who conducted the study believed that Pomegranate increases the levels of the enzyme *paraoxonase*, which has been found to break down oxidized cholesterol. (ref. 3-5) “The research has demonstrated that paraoxonase attacks not only oxidized cholesterol in the bloodstream, but also in atherosclerotic lesions, including fatty streaks, plaques, and atheromas.”

In a new study, researchers found that in patients with diseased arteries, as little as four ounces of Pomegranate juice a day for one year actually decreased the size of lesions in their carotid arteries... “It’s conceivable,” he says, “that increased consumption of pomegranates may even help atherosclerosis regress naturally, before patients have to resort to angioplasty and bypass surgery [5].

Another study, done in Israel, showed that Pomegranate juice reduced macrophage activity by 90 percent, resulting in less damage to cellular membranes. Macrophages engulfed with Low Density Lipoproteins swell, releasing free radicals, inflaming and obstructing blood vessels.

In another study researchers compared fermented Pomegranate juice and phenol-rich seed oil with red wine and green tea. Red wine and green tea have been widely studied and shown to possess the ability to block pro-inflammatory eicosanoid production. Eicosanoids are produced from Essential Fatty Acids and act as pro- and anti-inflammatory mediators. The study indicates that the phenols from Pomegranate are as effective as those from green tea, and are more active than the phenols in red wine in protection of cell membranes from oxidation and in anti-inflammatory activity [7].

Pomegranate is included for reduction of oxidized Low Density Lipoproteins and overall cholesterol levels, reduced platelet aggregation, plus other antioxidant and polyphenol support. Research indicates the potential healing of arterial lesions with long-term use.

Pomegranate is beneficial for retarding cellular aging and supports general well being.

Author/Yea	Design	Duration	N	Dosage	Results_(p≤0.05)
Cannetti M. et al. (1995) <sup>14</sup>	Randomized, doubleblind, placebo-controlled, type 2 hyperlipidemic subjects	2 years	69	10 mg/day	TC ↓ 17.6%, LDL-C 26.9% after 12 months
Mas R. et al. (1999) <sup>21</sup>	Randomized, doubleblind, placebo-controlled, successive dose increases, type 2 hyperlipidemic subjects	Two 12-week periods	437	5 and 10 mg/day periods	TC ↓ 13%, LDL-C ↓ 18.2% HDL-C ↑ 15.5% at 5 mg/day TC ↓ 17.4%, LDL-C ↓ 25.6% HDL-C ↑ 28.4%, TG ↓ 5.2% at 10 mg/day
Castano G, et al. (2000) <sup>22</sup>	Randomized, doubleblind, placebo-controlled, successive dose increases, type 2 hyperlipidemic, post-menopausal, female subjects	Two 12-week periods	244	5 and 10 mg/day periods	TC ↓ 12.6%, LDL-C ↓ 17.7%, HDL-C ↑ 16.5% at 5 mg/day TC ↓ 16.7%, LDL-C ↓ 25.2% HDL-C ↑ 29.3%, at 10 mg/day
Castano G, et al. (2001) <sup>23</sup>	Randomized, doubleblind, placebo-controlled, type 2 hyperlipidemic subjects	Two 12-week periods	179	5 and 10 mg/day periods	TC ↓ 12.8%, LDL-C ↓ 16.9% HDL-C ↑ 14.6% at 5 mg/day TC ↓ 16.2%, LDL-C ↓ 24.4% HDL-C ↑ 29.4%, at 10 mg/day
Pons P, et al. (1994) <sup>24</sup>	Randomized, doubleblind, placebo-controlled, successive dose increases, type 2 hyperlipidemic subjects	Three 8 week periods	22	5,10 and 20 mg/day periods	TC ↓ 14.1%, LDL-C ↓ 21.9% at 10 mg/day TC ↓ 23%, LDL-C ↓ 31.2% at 20 mg/day
Nikitin IP, et al. (2000) <sup>25</sup>	Randomized, doubleblind, comparative to besafibrate (400 mg) hyperlipidemic subjects	8 weeks	113	10 mg/day	Policosanol = TC ↓ 15%, LDL-C ↓ 18%, TG ↓ 15% Besafibrate = TC ↓ 8%, LDL-C ↓ 11%, TG ↓ 6%
Torres O, et al. (1995) <sup>26</sup>	Randomized, doubleblind, placebo-controlled, hyperlipidemic type 2 diabetic subjects	12 weeks	29	10 mg/day	TC ↓ 17.5%, LDL-C ↓ 21.8% -Glycemic control unaffected by treatment
Torres O, et al. (1995) <sup>26</sup>	Randomized, doubleblind, placebo-controlled, hyperlipidemic type 2 diabetic subjects	12 weeks	29	10 mg/day	TC ↓ 17.5%, LDL-C ↓ 21.8% -Glycemic control unaffected by treatment
Crespo N, et al. (1997) <sup>27</sup>	Randomized, doubleblind, placebo-controlled, hyperlipidemic type 2 diabetic subjects	12 weeks	21	10 mg/day	TC ↓ 28.9%, LDL-C ↓ 44.4 TC:HDL-C ratio ↓ 38.3%, LDL-C :HDL-C ratio ↓ 51.6% Glucose levels not significantly changed after therapy
Crespo N, et al. (1999) <sup>28</sup>	Randomized, doubleblind, comparative to lovastatin (20 mg) hyperlipidemic type 2 diabetic subjects	12 weeks	53	10 mg/day	,Policosanol = TC ↓ 14.2%, LDL-C ↓ 20.4% HDL-C ↑ 7.5% Lovastatin = TC ↓ 14%, LDL-C ↓ 16.8%, HDL-C (n/s)
Illnait J, et al. (1997) <sup>29</sup>	Randomized, doubleblind, comparative to simvastatin (5 mg) type 2 hyperlipidemic subjects	6 weeks	50	5 mg/day	Policosanol = TC ↓ 13%, LDL-C ↓ 21.1%, LDL-C:HDL-C ratio ↓ 26.4% Simvastatin = TC ↓ 20.3%, LDL-C ↓ 26.2%, LDL-C:HDL-C ratio ↓ 22.3%
Castano G, et al. (1999) <sup>30</sup>	Randomized, doubleblind, comparative to pravastatin (10 mg) hyperlipidemic subjects	8 weeks	68	10 mg/day	Policosanol = TC ↓ 13.9%, LDL-C ↓ 19.3%, HDL-C ↑ 18.4%, TG ↓ 14.1 Pravastatin= TC ↓ 11.8%, LDL-C ↓ 15.6%, HDL-C (ns), TG (ns)
Alcocer L, et al. (1999) <sup>31</sup>	Randomized, doubleblind, parallel, comparative to acipimox (750 mg) type 2 hyperlipidemic subjects	8 weeks	63	10 mg/day	Policosanol = TC ↓ 15.8%, LDL-C ↓ 21% Acipimox= TC ↓ 7%, LDL-C ↓ 7%
Pons P, et al. (1997) <sup>32</sup>	Randomized, doubleblind, parallel, comparative to probucol (1,000 mg) type 2 hyperlipidemic patients	8 weeks	30	10 mg/day	Policosanol = TC ↓ 18%, LDL-C ↓ 22.7%, TG ↓ 16.2% Probucol= TC ↓ 7.8%, LDL-C ↓ 11.8%, TG ↑ 4.7%
Batista J, et al. (1996) <sup>33</sup>	Randomized, singleblind, pilot clinical, hyperlipidemic patients	14 months	23	2 mg/day	TC ↓ 14.8%, LDL-C ↓ 15.6%
Castano G, et al. (1998) <sup>34</sup>	Open-Label, type 2 hyperlipidemic patients	8 weeks	54	20 mg/day	TC ↓ 16.9%, LDL-C ↓ 22.6%, HDL-C ↑ 20%, TG:HDL-C ratio ↓ 25.5%, LDL-C:HDL-C ratio ↓ 29.9%

**The Pomegranate fruit in this formula is from FutureCeuticals by Van Drunen Farms, with a 55:1 concentration. This source of Pomegranate is exceptionally rich in the antioxidant phyto-nutrients polyphenols with 40% polyphenols, including ellagic acid and gallic acid.**

**Constituents:** the polyphenols anthocyanins (delphinidin, malvidin, pelargonidin and cyanidin); vitamin C, ellagic acid, ellagitannin, chlorogenic acid, gallic acid, tannins, lignans, pectin, mucilage, inulin, pantothenic acid, potassium, and protein.

#### **TABLE: Published Clinical Studies on Policosanol**

### **BOTANICAL EXTRACTS**

#### **Guggul (*Commiphora mukul*):**

**Common Names:** Guggul, Guggulu, Indian Bedellium

Native to India, Guggul comes from the Mukul Myrrh tree. Guggul is a yellowish oleo-gum-resin.

Documented in ancient Ayurvedic texts as far back as 600 BC for obesity and lipid disorders. Guggul has been used for hundreds of years as an Ayurvedic herbal medicine and is well known as an effective treatment for arthritis. Over the last two decades, Guggul has been shown to be a highly potent hypolipidemic agent by Indian scientists. Guggul was recognized as an effective treatment for various types of arthritis.

**Dr. James Duke, for 27 years a PHd Botanist for the USDA and author of several books on herbs comments on Guggul. “I’ve seen studies documenting Gugulipid’s ability to reduce cholesterol by 14 to 27 percent in 4-12 weeks, without side effects” [17].**

#### **Traditional and Medical Uses:**

Guggul has documented use in ancient Ayurvedic texts as far back as 600 BC. It was recommended for obesity and lipid disorders.

Guggul is able to reduce blood cholesterol and triglycerides by increasing the uptake of LDL cholesterol from the blood by the liver, and enhancing cholesterol excretion through the bowels. It stimulates the liver’s metabolism of cholesterol.

Results from clinical experience and scientific research indicates a drop of about 20% in serum cholesterol in 4-8 weeks and about the same for triglycerides. The HDL levels rise about 30-60% over the same time period [33, 34, 36].

Another important action is that it stimulates the thyroid gland. A low functioning gland is often a factor in high cholesterol [35]. Support for the thyroid gland and it’s functions enhances the comprehensive nature of the formula.

Research suggests that Guggul also assists in preventing atherosclerotic plaque. It helps prevent free radical damage to the heart, has mild inhibitory affect on platelet aggregation and promotes fibrinolysis.

Anti-inflammatory action has been indicated in Guggul, useful in the treatment of rheumatoid arthritis, gout and cardiovascular disorders.

**Constituents:** The gum of guggul is a mixture of several steroid-lipids, oleo-gum-resin, volatile oil, bitter principle, Z-guggulsterone, E-guggulsterone. The gum resin of the Guggul plant is used therapeutically. It is important to separate Guggul into several components as the insoluble carbohydrate fraction can be toxic in large quantities. We use Gugulipid® by Sabinsa Corporation, a 5:1 concentrated extract with 2.5% total Guggulsterones. Gugulipid® is properly prepared for maximum efficacy and safety.

**Actions:** Aperient (appetite stimulant), alterative, rejuvenative, stimulant, cardi tonic, analgesic, expectorant, thyroid stimulating agent, antispasmodic, expectorant, astringent, antiseptic, bitter, demulcent, hypolipidemic agent, antirheumatic, carminative. Guggul stimulates digestion, has bitter and carminative actions, and is warming in nature.

## **Hawthorn Leaf, Berry and Flower (*Crataegus spp.*)**

Hawthorn is the premier cardio tonic and possesses powerful antioxidant activity; included in this formula for general cardiovascular support, connective tissue stabilization, and flavonoid content.

Hawthorn has been used and written about since the 1<sup>st</sup> Century AD. Hawthorn is well respected in Europe for cardiovascular health benefits. Hawthorn is a cardiovascular tonic in the truest sense of the word, working to increase blood supply to cardiac muscle and assisting in proper functioning; directly enhancing exercise tolerance. Hawthorn supports, nourishes and strengthens the connective tissues of the body due to the high flavonoid content.

Hawthorn is a heart food, and in the *Textbook of Natural Medicine*, it is referred to as "... a necessary food in the prevention and treatment of atherosclerosis. Increasing the intake of flavonoid compounds by taking crataegus extracts has numerous health-promoting effects, including reducing cholesterol levels and decreasing the size of existing atherosclerotic plaques. This again is probably a result of collagen stabilization" [14]. When the integrity of the blood vessels is weakened, cholesterol deposits are one of many disastrous results.

**The Hawthorn herb used in this formula is a 4-5:1 concentrate with a guarantee of 1.8% to 2.2% Vitexin in the phyto-nutrient group called flavonoids [9, 44, 45, 46].**

**Constituents:** Saponins; glycosides; flavonoids, flavanols including aglycones & o-glycosides, quercetin, kaempferol, flavone- O-glycosides, flavone- C-glycosides, vitexin, flavans, proanthocyanidins and pro-cyanidins; tannins; nitrogen-containing compounds including: Choline, acetylcholine, dopamine, adenine, adrenaline, noradrenaline; and acids including: Ascorbic, caffeic, and pentacyclic triterpenoid acids; ursolic, crataegolic and oleanolic [44, 45, 46].

**Actions:** Cardiotonic, cardioprotective, antioxidant, collagen stability, mild astringent, hypotensive, cholesterol reduction.

## **Andrographis (*Andrographis paniculata*)**

Andrographis stimulates the production of bile, an important piece in elimination of cholesterol from the body. This bitter herb is hepatoprotective, which is important when the liver is burdened due to elevated cholesterol levels. Andrographis also provides anti-inflammatory and antioxidant support.

**Common Names:** Andrographis, Chiretta, Kirata (Sanskrit), King of Bitters, Chuan Xin Lian (Chinese)- Literal Translation: "Thread the Heart Lotus."

The whole plant can be used including roots and leaf, or just arial parts. The leaf is used in this formula.

### **Traditional and Medical Uses of Plant:**

With its anti-inflammatory action, Andrographis helps protect the heart, and cardiovascular system and assists the body in mitigating the inflammatory aspect of immune response.

Cardiovascular benefits have been shown through the reduction of platelet aggregation, atherosclerotic activity and oxidative stress in myocardial tissue, as well as assisting in the lowering of blood pressure.

It has been shown in clinical research that Andrographis has phagocytic activity, and enhances non-specific immune response. Current research indicates reduction in symptoms and duration of cold and flu. Possible antibacterial properties of Andrographis extend to a variety of pathogens including: *S. aureus*, *Pseudomonas aeruginosa*, *Proteus vulgaris*, *Shigella dysenteriae*,

One study indicates its liver-protective and antioxidant properties are as active or more active than Milk Thistle in guarding the liver and lowering hepatic enzyme activity.

A native herb of India, Andrographis has been traditionally used as a bitter digestive tonic, stomachic, and liver supporter, and in the treatment of infectious disease, bronchitis, cholera, dysentery, diabetes, influenza, and jaundice. Also used to reduce heat, swelling, cough, urinary infections, sore throat, tonsillitis, abscesses, and sinusitis.

**The Andrographis used in this formula is a 10:1 concentration with 10 andrographolides.**

**Contraindications:** No significant adverse effects have been noted. High doses may cause gastric discomfort (high doses not used in this formula). Do not use during Pregnancy. Has shown some antifertility effects in high doses [15, 38, 39, 40, 41, 42, 43].

**Constituents:** Diterpenoid lactones called andrographolides, consisting of aglycones (such as andropholide) and glucosides (such as neoandrographolide and andrographiside), flavonoids, diterpene dimmers, bitter diterpenoid lactones, paniculide; A, B & C 14-deoxy-11-oxoandrograpolid; 14-deoxy-11-dehydroandrographolide.

**Actions:** Bitter tonic, choleric, hepatoprotective, immunostimulant, anti-inflammatory, antiplatelet, antipyretic, antioxidant, astringent, analgesic, antibacterial, abortifacient in large quantities.

### **Garlic Bulb Concentrate**

Ancient medicinal texts of the Orient contain references to garlic as both food and medicine. This precious bulb was also found in the tomb of the Egyptian Pharaoh Tutankhamun and, in the times of Ancient Greece, the physician Discorides spoke of garlic as being “clearing to the arteries”.

Garlic offers immense cardiovascular benefits that can help lower the risk of atherosclerosis, including the reduction of hardening arteries, which may ultimately lead to heart attack, stroke and other heart conditions.

Clinical studies have demonstrated that garlic improves the ratio of desirable High Density Lipoprotein (HDL) to harmful Low Density Lipoprotein (LDL), it lowers blood pressure, inhibits platelet aggregation, improves overall circulation and protects the coronary arteries against age related stiffening (63, 64).

Garlic is listed as an approved herb in the *German Commission E Monographs* as a treatment to support the lowering of cholesterol levels and helping to prevent age related cardiovascular problems. It is approved for similar use in the UK and France (9).

Australian physicians conducted 8 trials, mostly over a period of 12 weeks each, on a total of 415 hypertensive patients using placebo supplemented controls. They found a significant decrease in both systolic and diastolic blood pressure in the Garlic treated subjects (67).

Doctor Indrajit Das, of London’s Charing Cross and Westminster Medical School, found that garlic directly effects arterial walls by releasing nitric oxide which actually has an arterial relaxing effect (65).

**The Garlic concentrate used in this formula is a fresh freeze-dried concentrate from Van Drunen Farms and has 12,000 ppm of Allicin.**

**Constituents:** Garlic contains more than 200 compounds identified to date. Ajoene, found in crushed Garlic, reduces the stickiness of platelets in the blood plasma (66). The organosulfur compounds in Garlic appear to be responsible for its ability to slow cholesterol synthesis, lower blood pressure, reduce atherosclerosis and inhibit platelet aggregation. They also support and help protect the liver and glutathione (19, 20).

**Actions:** anti-bacterial, anti-inflammatory and antioxidant

## **SUPPORTIVE FIBER FOODBASE:**

Cholesterol is carried from the body in bile and dietary fiber. Cholesterol Response™ combines several fiber-rich whole foods to assist in the final aspect of cholesterol regulation. Using fiber to ensure that intestinal cholesterol is appropriately carried from the body is an important aspect of cholesterol management.

### **Rice Bran**

Rice bran is a nutrient-rich source of dietary fiber, containing insoluble fiber (cellulose) and soluble fiber (hemicellulose). Studies show Rice Bran fiber lowers cholesterol and other fats when included as part of the diet.

### **Apple Pectin Fiber**

Pectin fiber helps protect against cardiovascular disease by lowering cholesterol and facilitating its elimination. Pectin is a soluble dietary fiber that can bind with LDL cholesterol and carry it from the body.

### **Nutrim™ Oat Beta-Glucan fiber: US Patent Number 6,060,519**

Oats have been recognized to be effective in helping to lower serum cholesterol levels since 1963. Oats, especially in the form known as Nutrim%, are a source of soluble fiber. Soluble fiber has been shown to help reduce cholesterol and lower the glycemic index of foods (how quickly carbohydrate rich foods will raise blood sugar and trigger release of insulin). Nutrim% was developed by George Inglett of the USDA for the Center for Agricultural Utilization and Research. The FDA has recently recognized the importance of oat soluble fiber beta-glucans and now allows health claims on foods containing oat beta-glucans, in daily dosages in the range of 750 mg. and up [61].

### **How does oat soluble fiber beta-glucan lower cholesterol?**

The bile acids in the intestines mix with the soluble fiber beta-glucans, preventing their absorption. The soluble fiber then carries them from the body. The liver senses the reduction of bile acids and responds by taking cholesterol from the blood and sending it to the intestines, thereby reducing serum cholesterol levels.

A second mechanism of action is that during the fermentation of the soluble fiber in the intestines, the short chain fatty acid propionate is enhanced. Propionate is absorbed from the colon through the portal vein and has been shown to inhibit HMG CoA reductase, the rate-limiting enzyme for cholesterol biosynthesis [60, 61, 62]. Nutrim™ has also shown beneficial action on glucose absorption and weight management as well as antioxidant activity.

### ***Laminaria digitata***

This sea vegetable, also called Kelp, is included for trace minerals and other beneficial nutrients. Elevations in cholesterol can be the result of hypothyroidism; kelp is highly supportive to the thyroid gland. *Laminaria* is rich in trace minerals, iodine, macro minerals and electrolytes such as potassium, calcium and magnesium.

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