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URINOZINC - PROSTAHELP  
HAIR - HORMONEHELP  
PROSTA POTENCY PLUS  
COLON - HELP  
OPTIMUM ENERGY - ANTIOXIDANT FORMULA

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Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied  
Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

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5/18/98

NOTIFICATION OF STATEMENTS  
OF NUTRITIONAL SUPPORT

This notification is filed pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of supplement	HEART-CIRCULATORY-HELP
Dietary ingredients	VITAMIN E, NIACIN, VITAMIN B6, FOLATE (FOLIC ACID), VITAMIN B12, MAGNESIUM, L-ARGININE, CRATAEGUS OXYACANTHA, AMMI VISNAGA, CURCUMA LONGA, GINKGO BILOBA, COMMIPHORA MUKUL.
Statements of nutritional support for the supplement	<ol style="list-style-type: none"> <li>1. A DIETARY SUPPLEMENT THAT HELPS TO PROMOTE A HEALTHY HEART AND CIRCULATORY SYSTEM</li> <li>2. SOME OF THE INGREDIENTS IN THIS UNIQUE FORMULA HAVE BEEN USED FOR MANY CENTURIES BY ANCIENT CIVILIZATIONS TO HELP THE CIRCULATORY SYSTEM.</li> <li>3. HEART-CIRCULATORY-HELP CONTAINS FIVE PHYTONUTRIENTS: CRATAEGUS OXYACANTHA, AMMI VISNAGA, CURCUMA LONGA, GINKGO BILOBA, AND COMMIPHORA MUKUL, WHICH HAVE BEEN INDIVIDUALLY SHOWN TO BE BENEFICIAL TO THE CARDIOVASCULAR SYSTEM IN A WEALTH OF SCIENTIFIC STUDIES THROUGHOUT THE WORLD.</li> <li>4. IT CONTAINS VITAMIN E THAT IS POSTULATED TO STRENGTHEN THE BLOOD VESSEL WALLS, PROTECTING LDL CHOLESTEROL FROM FREE RADICAL DAMAGE, AND PREVENTING THE CLUMPING OF BLOOD CELL FRAGMENTS CALLED PLATELETS. THERE IS ALSO EVIDENCE THAT VITAMIN E INCREASES THE PROSTAGLANDIN'S PRODUCTION, THEREFORE, HELPING TO MAINTAIN HEALTHY ARTERY WALLS. IT IS CONSIDERED ONE OF THE MOST IMPORTANT NUTRIENTS TO MAINTAIN A HEALTHY CARDIOVASCULAR SYSTEM. IT IS ALSO HIGHLY REGARDED FOR ITS CAPACITY TO</li> </ol>

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DECREASE PLATELET AGGREGATION. IT ALSO HAS POSITIVE IMMUNE ENHANCING EFFECTS DIRECTLY RELATED TO ITS ANTIOXIDANT FUNCTION WHICH PROTECTS THE FATTY MEMBRANES OF IMMUNE CELLS.

5. IT IS WELL KNOWN THAT NIACIN ACTS IN THE NERVOUS SYSTEM AND ON BLOOD LIPIDS AND GLUCOSE. NIACIN CAN HELP MAINTAIN HEALTHY CHOLESTEROL AND TRIGLYCERIDE LEVELS. NIACIN (VITAMIN 3) IS UNIQUE AMONG THE B VITAMINS BECAUSE IT CAN BE MANUFACTURED BY THE BODY HELPING THE CIRCULATORY SYSTEM. IT IS ONE OF THE OLDEST KNOWN NUTRIENTS. IN LARGE AMOUNTS (2 OR 3 GRAMS A DAY), NIACIN SHOULD BE TAKEN ONLY UNDER A DOCTOR'S SUPERVISION ON ACCOUNT OF ITS DIRECT ACTION ON THE LIVER.
6. VITAMIN B6: IS A VERY IMPORTANT VITAMIN. IT IS INVOLVED IN THE PROCESSING OF CARBOHYDRATES, FATS AND PROTEINS. ITS MAIN FUNCTION IS RELATED TO PROTEIN AND ITS BUILDING BLOCKS, THE AMINO ACIDS. VITAMIN B6 IS INVOLVED IN THE MANUFACTURING OF PROTEIN RELATED COMPOUNDS SUCH AS HORMONES, HEMOGLOBIN IN RED BLOOD CELLS AND MANY ENZYMES. TOGETHER WITH FOLIC ACID, VITAMIN B12, AND VITAMIN B6 HELPS TO DIMINISH THE LEVELS OF HOMOCYSTEINE FROM THE BLOOD CIRCULATION HELPING TO MAINTAIN HEALTHY BLOOD VESSELS.
7. FOLIC ACID: BLOOD LEVELS OF HOMOCYSTEINE BECOME ELEVATED IF THE DIETARY FOLIC ACID INTAKE IS NOT ADEQUATE. FOLIC ACID INTAKE IN THE 250-400 MCG RANGE WERE ASSOCIATED WITH A SLIGHT ELEVATION OF BLOOD HOMOCYSTEINE. THIS STUDY AND OTHERS HAVE SHOWN THAT THE AMOUNT OF DIETARY FOLIC ACID THAT ARE REQUIRED TO PREVENT ELEVATIONS OF BLOOD HOMOCYSTEINE ARE 350-400 MCG PER DAY ON FOLIC ACID TOGETHER WITH 3 TO 3.5 MG OF VITAMIN B6.
8. VITAMIN B12: VITAMIN B12 IS NECESSARY FOR NORMAL PROCESSING OF CARBOHYDRATES, PROTEINS AND FAT IN THE BODY AND IS ONE OF THE MOST IMPORTANT VITAMINS NECESSARY TO REDUCE THE LEVEL OF HOMOCYSTEINE TOGETHER WITH VITAMIN B6 AND FOLIC ACID.
9. MAGNESIUM: ALTHOUGH ALL OF THE MECHANISMS FOR MAGNESIUM'S EFFECTS ON THE CARDIOVASCULAR SYSTEM ARE NOT FULLY UNDERSTOOD, SEVERAL FUNCTIONS HAVE BEEN IDENTIFIED AND PLACE MAGNESIUM AT THE FOREFRONT IN CARDIOVASCULAR HEALTH MAINTENANCE.

MAGNESIUM COMPETES WITH CALCIUM. IT HELPS REGULATE CALCIUM MOVEMENT ACROSS AND WITHIN CELL MEMBRANES OF CARDIAC AND VASCULAR TISSUES, AND IS ESSENTIAL TO NEUROMUSCULAR ACTIVITY, INCLUDING MUSCULAR CONTRACTION OF THE MYOCARDIUM AND VASCULAR TISSUES.

THE EFFECTS OF MAGNESIUM INCLUDE ITS ABILITY TO REDUCE VASCULAR RESISTANCE. BLOOD COAGULABILITY ALSO IS AFFECTED BY MAGNESIUM. INCLUDING INHIBITION OF PLATELET AGGREGATION AND PROLONGED CLOTTING TIME.

MAGNESIUM ALSO HELPS MAINTAIN A HEALTHY HEARTBEAT EITHER BECAUSE OF A DIRECT EFFECT ON CARDIAC CONDUCTION AND EXCITABILITY, OR BECAUSE IT STABILIZES OTHER IONS



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(SODIUM, CALCIUM, AND POTASSIUM), MAINTAINS CARDIOVASCULAR HEMODYNAMICS, AND INFLUENCES MYOCARDIAL METABOLISM. MAGNESIUM IMPROVES MYOCARDIAL PERFORMANCE BY LOWERING SYSTEMIC VASCULAR RESISTANCE. IN ADDITION, MAGNESIUM SUPPLEMENTATION INDUCES CORONARY VASODILATION AND IMPROVES CORONARY BLOOD SUPPLY.

THE CURRENT RESEARCH PROVIDES SUBSTANTIAL EVIDENCE THAT MAGNESIUM EXERTS A STRONG MYOCARDIAL PROTECTIVE EFFECT. FUTURE RESEARCH IS LIKELY TO UNCOVER OTHER CARDIO-PROTECTIVE FUNCTIONS OF MAGNESIUM.

10. L-ARGININE: AMINO ACIDS ARE THE SMALLEST MOLECULES THAT COMPRISE A PROTEIN. REFERRED TO AS THE BUILDING BLOCKS OF PROTEIN, THERE ARE 22 MAJOR AMINO ACIDS COMPRISING OVER THREE-QUARTERS OF THE BODY'S SOLID WEIGHT, AMINO ACIDS ARE BROKEN DOWN INTO "ESSENTIALS" AND "NON ESSENTIALS". "ESSENTIALS" ARE THOSE THAT THE BODY IS INCAPABLE OF MANUFACTURING, "NON ESSENTIALS" THOSE THAT YOUR BODY CAN PRODUCE. THE "ESSENTIALS" MUST BE DERIVED FROM FOODS WHILE THE REMAINING "NON ESSENTIAL" AMINO ACIDS CAN BE OBTAINED THROUGH A METABOLIC TRANSFORMATION OF THE "ESSENTIALS". RECENT RESEARCH INDICATES THAT "NON ESSENTIAL" AMINO ACIDS MAY BE NEEDED IN GREATER QUANTITIES THAN THE BODY CAN PRODUCE FROM THE "ESSENTIALS". THE "ESSENTIAL AMINO ACIDS" ARE: ISOLEUCINE, LEUCINE, LYSINE, METHIONINE, PHENYLALANINE, THREONINE, TRYPTOPHAN AND VALINE ALONG WITH HISTIDINE, WHICH IS ESSENTIAL FOR CHILDREN. ARGININE IS CONSIDERED "SEMI ESSENTIAL". ALL TWENTY TWO AMINO ACIDS ARE REQUIRED BY THE BODY FOR THE SYNTHESIS OF PROTEIN. INDIVIDUALLY THEY PAY A VITAL PART IN TODAY'S MODERN NUTRITIONAL PROGRAMS.

L-ARGININE IS A CONDITIONALLY ESSENTIAL AMINO ACID WHICH MAY PLAY A CRITICAL ROLE IN PROTEIN METABOLISM, GROWTH-HORMONE RELEASE, AND SEXUAL FUNCTION IN MEN. ARGININE IS ALSO A PRECURSOR USED IN CREATINE PRODUCTION.

L-ARGININE IS THE PRECURSOR OF ENDOGENOUS NITRIC OXIDE (NO), WHICH IS A POTENT VASODILATOR ACTING VIA THE INTRACELLULAR SECOND-MESSENGER cGMP. IN HEALTHY HUMANS, L-ARGININE INDUCES PERIPHERAL VASODILATION AND INHIBITS PLATELET AGGREGATION DUE TO AN INCREASED N.O. PRODUCTION.

11. CRATAEGUS OXYACANTHA ( ENGLISH HAWTHORN) (SEED & FLOWER):  
CONSTITUENTS
- FLAVONOIDS, INCLUDING QUERCITIN, VITEXIN, RUTIN, AND HYPEROSIDE
  - OLIGOMERIC PROCYANIDINS (OPCs)
  - CARDIOTONIC AMINES
  - (-) EPICATECHIN
  - TRITERPENE ACIDS
  - VITAMIN C (IN THE BERRIES)
12. AMMI VISNAGA (SEED & FLOWER)  
THE PARTS OF THE PLANT USED ARE THE FRUITS AND THE FLOWERING TOPS; FOR THEIR IMPORTANCE THESE PARTS WILL BE



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INVESTIGATED FROM THE CHEMICAL AND BIOLOGICAL POINT OF VIEW.

#### CHEMISTRY

THE CHEMICAL STUDY OF AMMI VISNAGA BEGAN IN 1879 WITH THE ISOLATION OF A YELLOW COMPOUND NAMED KHELLIN, WHICH WAS ONE OF THE MAIN COMPONENTS FROM THE SEEDS AND THE AERIAL PARTS OF THIS PLANT; ALONG WITH KHELLIN AT THAT TIME, OTHER SUBSTANCES WERE ISOLATED BUT THEIR STRUCTURAL DETERMINATION WAS CARRIED OUT ABOUT 60 YEARS LATER BY SPAETH AND GRUBER; THEY, STARTING FROM THE CRUDE COMPONENTS (VISNAGANE) DESCRIBED IN THE PRIOR ART, DEFINED THE STRUCTURES OF KHELLIN, VISNAGINE AND KHELLOLGLUCOSIDE. SUBSEQUENTLY OTHER COMPONENTS WERE ISOLATED AND CHARACTERIZED BY OTHER AUTHORS LIKE: AMMIOL, KHELLINOL, VISAMMIOL, SAMIDIN, DIHYDROSAMIDIN, VISNADINE, AMMIOL-GLUCOSIDE. DEGRADATION PRODUCTS WERE ALSO IDENTIFIED, SUCH AS KHELLATON, METHYLKHELLATON, KHELLINON AND VISNAGINON. FROM THE SAME PART OF THE PLANT, OF COURSE, OTHER COMPONENTS, VERY COMMON IN THE VEGETAL KINGDOM, HAVE BEEN ISOLATED SUCH AS THE FLAVON ASACETIN, COUMARINS, PHYTOSTEROLS, TRIGLICERIDES, SUGARS AND PROTEINS

THE SUBSTANCES RESPONSIBLE FOR THE BIOLOGICAL ACTIVITY ARE THE FURANOCHROMONES AND THE SUBSTITUTED COUMARINES. THE MOST IMPORTANT COMPONENTS OF THESE TWO CLASSES ARE KHELLIN AND VISNADINE. THEREFORE ALL THE EFFORT HAS BEEN MADE TO AMELIORATE THEIR EXTRACTION, PURIFICATION PROCESSES AND TOTAL SYNTHESIS. THE SYNTHESIS OF KHELLIN WAS FIRSTLY REALIZED BY REED ET AL. AND BY YAMASHITA ET AL. HOWEVER, UP TO NOW THE PRODUCT IS STILL OBTAINED BY EXTRACTION. THE CONTENT OF THE FURANOCHROMONES IN THE AERIAL PARTS OF AMMI VISNAGA VARIES FROM 4 TO 2% WHILE THE KHELLIN CONTENT VARIES FROM 0.3 TO 1.2%.

HOWEVER, THE DISCOVERY OF VASODILATING AND CORONARODILATING PROPERTIES OF THE EXTRACT AND ITS ISOLATED ACTIVE PRINCIPLES (LIKE KHELLIN AND VISNADINE), DATES BACK TO THE CURRENT CENTURY. KHELLIN EXERTS A DIRECT ACTION ON THE SMOOTH MUSCULATURE.

#### 13. CURCUMA LONGA (TURMERIC):

ETYMOLOGY AND HISTORY: TURMERIC IS THE COMMON NAME FOR CURCUMA LONGA AND HAS BEEN USED AS A SPICE AND NATURAL DYE FOR THOUSANDS OF YEARS. TURMERIC IS NATIVE ASIA AND INDIA WHERE IT IS CURRENTLY CULTIVATED. TURMERIC HAS BEEN USED FOR AS LONG AS 2500 YEARS AS IT WAS LISTED IN ASSYRIAN HERBAL CIRCA 600 BC. CURCUMA WAS ALSO MENTIONED BY DIOSCORIDES.

COLLECTION: CULTIVATED PRIMARILY IN INDIA

PREPARATION AND STORAGE: TURMERIC IS TINCURED AND POWDERED FOR ENCAPSULATION.

DOSAGE: 200 TO 400 MG CURCUMIN 3 TIMES A DAY.

MODERN STUDIES: TURMERIC HAS THREE MAJOR PHYTOCHEMICAL COMPOUNDS, CALLED CURCUMINOIDS, THAT GIVE TURMERIC ITS BRIGHT YELLOW-ORANGE COLOR. THESE CURCUMINOIDS (OF WHICH CURCUMIN IS THE MOST SIGNIFICANT) HAVE BEEN THE FOCUS OF MORE THAN ONE HUNDRED DIFFERENT



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LABORATORY AND CLINICAL STUDIES INDICATING THEIR SAFETY, AND ANTIOXIDANT EFFECTS; PLUS THEIR POTENTIAL TO HELP MAINTAIN A HEALTHY HEART.

IN A SEVEN DAY STUDY INVOLVING 10 HEALTHY SUBJECTS ISSUED 500 MG OF CURCUMINOIDS DAILY, CURCUMINOIDS WERE SHOWN TO BE A SAFE AND EFFECTIVE ANTIOXIDANT IN PREVENTING SERUM LIPID PEROXIDATION.

BASED ON A STUDY, CURCUMIN INHIBITS LIPID PEROXIDASE. HYDROXAL RADICALS WERE MOST SIGNIFICANTLY INHIBITED. THE INHIBITION OF OXYGEN RADICALS WAS MORE POTENT THAN VITAMIN E BUT LESS POTENT THAN VITAMIN C. BOTH THE ESSENTIAL OIL AND CURCUMIN HAVE BEEN SHOWN TO INCREASE BILE SECRETION.

CURCUMIN INTERFERES WITH INTESTINAL CHOLESTEROL UPTAKE, INCREASING THE CONVERSION OF CHOLESTEROL INTO BILE ACIDS, AND INCREASING THE EXCRETION OF BILE ACIDS (INTERNATIONAL JOURNAL OF VITAMIN NUTRITIONAL RESEARCH (61:364-9 1991)

CURCUMIN PREVENTS PLATELET AGGREGATION BY INTERFERING WITH FORMATION OF THROMBOXANES. CURCUMIN INCREASES LEVELS OF PROSTACYCLIN, THE BODY'S NATURAL INHIBITOR OF PLATELET AGGREGATION.

ANTI-PLATELET AGGREGATOR RESEARCH SUGGESTS THAT CURCUMIN SELECTIVELY INHIBITS THROMBOXANE PRODUCTION WHILE SPARING PROSTACYCLIN.

THE ASTOUNDING HEALTH BENEFITS OF CURCUMINOIDS HAVE BEEN DOCUMENTED AMONG MORE THAN 200 PUBLISHED MEDICAL STUDIES. THIS INCLUDES SUCH DISTINGUISHED MEDICAL JOURNALS AS *THE JOURNAL OF THE AMERICAN COLLEGE OF NUTRITION*.

14. GINKGO BILOBA:

HISTORIC OVERVIEW

THE STANDARDIZED GINKGO BILOBA EXTRACT IS FROM THE LEAVES OF GINKGO BILOBA L., FAMILY GINKGOACEAE. THE GINKGO SPECIES HAS SURVIVED FOR OVER 200 MILLION YEARS, AND SOME GINKGO TREES LIVE TO BE OVER 1,000 YEARS OLD. ALTHOUGH THE GINKGO TREE IS A VERY OLD ONE, THE STANDARDIZED EXTRACT PREPARED FROM ITS LEAVES IS QUITE NEW, HAVING BEEN DEVELOPED IN THE PAST 20 YEARS. TODAY THE STANDARDIZED GINKGO BILOBA EXTRACT MADE FROM GINKGO LEAVES ARE AMONG THE BEST-SELLING HERBAL PRODUCTS IN THE WORLD AND IS A WELL ESTABLISHED PRODUCT IN THE UNITED STATES.

THE CHINESE, WHO HAVE RECOGNIZED THE TREE'S UNIQUE STAMINA AND LONGEVITY, HAVE USED GINKGO NUTS FOR THOUSANDS OF YEARS TO INCREASE SEXUAL ENERGY AND GENERALLY PROMOTE LONGEVITY. TODAY THE ANCIENT GINKGO HAS SPARKED RENEWED INTEREST THROUGHOUT THE WORLD BECAUSE RESEARCHERS HAVE ISOLATED CHEMICAL COMPOUNDS FROM GINKGO THAT SHOW STARTLING EFFECTS IN HUMANS. THESE COMPOUNDS REGULATE BLOOD FLOW TO THE BRAIN, LEGS AND OTHER EXTREMITIES AND CONTROL LEVELS OF VARIOUS NEUROTRANSMITTERS IN THE BRAIN, THUS HELPING TO ENHANCE MEMORY FUNCTION AND COUNTERACT LACK OF ALERTNESS.



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THESE SAME COMPOUNDS ALSO BLOCK A SUBSTANCE CALLED PLATELET ACTIVATING FACTOR (PAF) WHICH, OVER-STIMULATES THE IMMUNE SYSTEM.

VASCULAR: THE PRIMARY PROPERTY OF GINKGO IS TO INCREASE THE FLOW OF BLOOD INTO AREAS PREVIOUSLY DEPRIVED OF THIS LIFE-GIVING SUBSTANCE TO ONE DEGREE OR ANOTHER, INCLUDING THE BRAIN, THE LOWER LIMBS, ALL ARTERIES, VEINS, EVEN THE SMALLEST CAPILLARIES. DECREASED BLOOD FLOW TO THE BRAIN CAN ADVERSELY AFFECT MEMORY, CONCENTRATION, INTELLECTUAL ABILITY, VISION, EQUILIBRIUM AND BALANCE. IT MAY ALSO LEAD TO MENTAL CONFUSION.

HEARING: DISTURBANCE OF BALANCE AND HEARING WEAKNESS MAY RESULT FROM LACK OF PROPER BLOOD CIRCULATION. THESE CAN ALSO BE CAUSED BY FREE RADICAL DAMAGE. THESE PROBLEMS THAT HAS RESULTED FROM A DISTURBANCE IN BLOOD SUPPLY (AND MOST SUCH PROBLEMS HAVE A VASCULAR COMPONENT) CAN BE BENEFICIALLY AFFECTED BY THE INGESTION OF GINKGO BILOBA EXTRACT.

15. GUGULIPID: GUGULIPID IS THE STANDARDIZED EXTRACT OF THE MUKUL MYRRH TREE (COMMIPHORA MUKUL) THAT IS NATIVE TO INDIA. THE ACTIVE COMPONENTS OF GUGULIPID ARE TWO COMPOUNDS, Z-GUGULSTERONE AND E-GUGGULSTERONE. SEVERAL CLINICAL STUDIES HAVE CONFIRMED THAT GUGULIPID HAS AN ABILITY TO HELP MAINTAIN HEALTHY CHOLESTEROL AND TRIGLYCERIDE LEVELS.

THE MECHANISM OF GUGULIPID'S ACTION IS ITS ABILITY TO INCREASE THE LIVER'S METABOLISM OF LDL-CHOLESTEROL; GUGGULSTERONE INCREASES THE UPTAKE OF LDL-CHOLESTEROL FROM THE BLOOD BY THE LIVER.

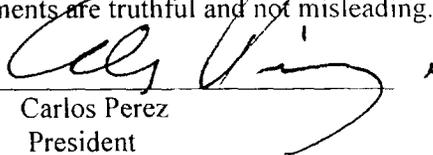
THE INTAKE OF GUGULIPID IS BASED ON ITS GUGGULSTERONE CONTENT. CLINICAL STUDIES HAVE DEMONSTRATED THAT GUGULIPID EXTRACTS STANDARDIZED TO CONTAIN 25 MILLIGRAMS OF GUGGULSTERONE PER TABLET TAKEN THREE TIMES PER DAY CAN HELP MAINTAIN HEALTHY CHOLESTEROL LEVELS.

THE ACTIVE COMPONENTS ARE BELIEVED TO BE TWO STEROIDS "GUGGULSTERONES Z AND E". OUR GUGULIPID IS THE STANDARDIZED HIGH QUALITY EQUIVALENT TO 25 MG. OF GUGGULSTERONE.

THE GUGGULSTERONES INCREASE THE UPTAKE OF LDL CHOLESTEROL FROM THE BLOOD OF THE LIVER AND STIMULATE THE THYROID FUNCTION THUS INCREASING THE LIVER'S METABOLISM OF LDL.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

By

  
Carlos Perez  
President