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SUMMARY OF CLINICAL STUDIES

Product	Omega Cardioprotector
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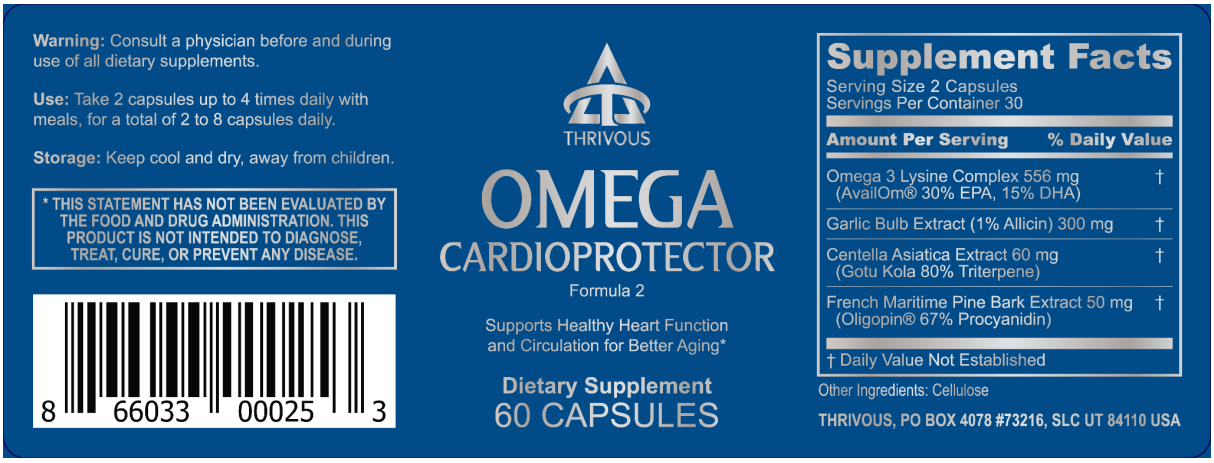
Label



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Centella Asiatica to Enhance Circulation

Centella Asiatica (Gotu Kola) supplements (dosage standardized between 60 and 180 mg triterpenoid daily) may enhance circulation, according to these clinical studies on humans:

- Total triterpenic fraction of Centella asiatica in the treatment of venous hypertension: a clinical, prospective, randomized trial using a combined microcirculatory model. In 2001, this study found that “important symptomatologic effects (evaluated by subjective scores) followed [Centella Asiatica] administration, especially at the higher dose level, while no effect was obtained with placebo.” Participants used 60 to 120 mg triterpenoid daily.

- Microcirculatory effects of total triterpenic fraction of Centella asiatica in chronic venous hypertension: measurement by laser Doppler, TcPO2-CO2, and leg volumetry. In 2001, this study found that Centella Asiatica “improves microcirculation and leg volume.” Participants used 120 mg triterpenoid daily for 6 weeks.

- Evaluation of treatment of diabetic microangiopathy with total triterpenic fraction of Centella asiatica: a clinical prospective randomized trial with a microcirculatory model. In 2001, this study found “a significant improvement of microcirculatory parameter in patients treated with [Centella Asiatica].” Participants used 120 mg triterpenoid daily for 6 months.

- Treatment of diabetic microangiopathy and edema with total triterpenic fraction of Centella asiatica: a prospective, placebo-controlled randomized study. In 2001, this study found that “decrease in capillary filtration and edema is associated with symptomatic improvement” during supplementation with Centella Asiatica. Participants used 120 mg triterpenoid daily for 12 months.

- Treatment of edema and increased capillary filtration in venous hypertension with total triterpenic fraction of Centella asiatica: a clinical, prospective, placebo-controlled, randomized, dose-ranging trial. In 2001, this study found that “the improvement of signs and symptoms by [Centella Asiatica] observed in patients with venous hypertension was well correlated with the improvement of CFR and ankle edema.” Participants used 90 to 180 mg triterpenoid daily for 4 weeks.

- Flight microangiopathy in medium- to long-distance flights: prevention of edema and microcirculation alterations with total triterpenic fraction of Centella asiatica. In 2001, this study found that “variations in all parameters were milder in the [Centella Asiatica] group” while traveling in economy class flights up to 10 hours. Participants used 180 mg triterpenoid daily for 4 days.

- Effects of the total triterpenic fraction of Centella asiatica in venous hypertensive microangiopathy: a prospective, placebo-controlled, randomized trial. In 2001, this study found that “venous microangiopathy was improved by [Centella Asiatica] treatment.” Participants used 120 mg triterpenoid daily for 8 weeks.

This systematic review confirms that Centella Asiatica (Gotu Kola) supplements may enhance circulation:

- A Systematic Review of the Efficacy of Centella asiatica for Improvement of the Signs and Symptoms of Chronic Venous Insufficiency. In 2013, this review observed that “Centella asiatica may be beneficial for improving signs and symptoms of [chronic venous insufficiency].”

French Maritime Pine Bark to Support Healthy Heart Function

French Maritime Pine Bark supplements may support healthy heart function, according to this clinical study on humans:

- Effects of low molecular weight procyanidin rich extract from french maritime pine bark on cardiovascular disease risk factors in stage-1 hypertensive subjects: Randomized, double-blind, crossover, placebo-controlled intervention trial. In 2016, this study found that a French Maritime Pine Bark supplement "raised High Density Lipoprotein-cholesterol (HDL-c) … [and] reduced the systolic [Blood PRessure] … and decreased ox-LDL concentrations." Participants used 150 mg of the Oligopin extract daily for five weeks.

Clinical studies of another branded extract of French Maritime Pine Bark have also demonstrated cardiovascular benefits. The owner of that brand claims that its clinical results are exclusive to its extract. Thrivous disagrees with that assessment. But we have chosen to honor the request not to reference its clinical studies here.

The Oligopin extract of French Maritime Pine Bark may be safer than alternatives according to this clinical study:

- Evaluation of the systemic toxicity and mutagenicity of OLIGOPIN®, procyanidolic oligomers (OPC) extracted from French Maritime Pine Bark extract. In 2018, this study observed that Oligopin may be "less systemically toxic than other [extracts of French Maritime Pine Bark] previously evaluated in subchronic studies, and comparable to proanthocyanidins extracted from grape seeds, which are widely used as nutritional supplement ingredients."

Garlic to Support Healthy Cholesterol and Heart Function

Garlic supplements (dosage standardized between 3 and 8 mg allicin daily) may support healthy cholesterol and heart function, according to these clinical studies on humans:

- Randomized trial evaluating the effect of aged garlic extract with supplements versus placebo on adipose tissue surrogates for coronary atherosclerosis

progression. In 2018, this study observed that heart adipose tissues "are mediators of metabolic risk" and found that Garlic "is associated with favorable effects on reducing the progression rate of adipose tissue volumes".

- Does Garlic Supplementation Control Blood Pressure in Patients with Severe Coronary Artery Disease? A Clinical Trial Study. In 2016, this study found that "treatment with garlic-based drugs can be an effective treatment for controlling [blood pressure]".

- The effect of aged garlic extract on blood pressure and other cardiovascular risk factors in uncontrolled hypertensives: the AGE at Heart trial. In 2016, this study found that Garlic supplementation "is effective in reducing peripheral and central blood pressure … and has the potential to improve arterial stiffness, inflammation, and other cardiovascular markers in patients with elevated levels".

- Aged garlic extract reduces blood pressure in hypertensives: a dose-response trial. In 2013, this study found Garlic supplementation "to be an effective and tolerable treatment in uncontrolled hypertension, and may be considered as a safe adjunct treatment to conventional antihypertensive therapy".

- Aged garlic extract improves adiponectin levels in subjects with metabolic syndrome: a double-blind, placebo-controlled, randomized, crossover study. In 2013, this study found that Garlic supplementation "might be a useful, novel, nonpharmacological therapeutic intervention to … prevent cardiovascular complications".

- Effects of Allium sativum (garlic) on systolic and diastolic blood pressure in patients with essential hypertension. In 2013, this study found that Garlic supplementation resulted in "significant decrease in both Systolic and Diastolic blood pressure".

- Aged garlic extract lowers blood pressure in patients with treated but uncontrolled hypertension: a randomised controlled trial. In 2010, this study found that Garlic supplementation "is superior to placebo in lowering systolic blood pressure".

- The effects of time-released garlic powder tablets on multifunctional cardiovascular risk in patients with coronary artery disease. In 2010, this study found that Garlic supplementation “results in the significant decrease of cardiovascular risk”.

- Effects of garlic consumption on plasma and erythrocyte antioxidant parameters in elderly subjects. In 2008, this study found that “LDL cholesterol was found to be significantly lower” with Garlic supplementation.

- Lipid-lowering effects of time-released garlic powder tablets in double-blinded placebo-controlled randomized study. In 2008, this study found “cardioprotective action of garlic preparations”.

- Effects of anethum graveolens and garlic on lipid profile in hyperlipidemic patients. In 2007, this study found that Garlic supplementation “has significant favorable effect on cholesterol, LDL-cholesterol, and HDL-cholesterol”.

- Effect of garlic (Allium sativum) oil on exercise tolerance in patients with coronary artery disease. In 2005, this study found that Garlic supplementation “reduced heart rate at peak exercise and also significantly reduced the work load upon the heart resulting in better exercise tolerance”.

- Garlic supplementation prevents oxidative DNA damage in essential hypertension. In 2005, this study found that Garlic supplementation resulted in “reducing blood pressure and counteracting oxidative stress, and thereby, offering cardioprotection”.

- Inhibiting progression of coronary calcification using Aged Garlic Extract in patients receiving statin therapy: a preliminary study. In 2004, this study found that Garlic supplementation may “inhibit the rate of progression of coronary calcification”.

These clinical study reviews confirm that Garlic supplements may support healthy cholesterol and heart function:

- Effect of garlic supplement in the management of type 2 diabetes mellitus

(T2DM): a meta-analysis of randomized controlled trials. In 2017, this meta-analysis of 9 studies observed that “garlic supplement plays positive and sustained roles in blood glucose, total cholesterol, and high/low density lipoprotein regulation”.

- An umbrella review of garlic intake and risk of cardiovascular disease. In 2016, this review of 9 meta-analyses observed that “garlic preparations as well as garlic exerted some positive effects on indicators and biomarkers of cardiovascular disease”.

- Garlic Lowers Blood Pressure in Hypertensive Individuals, Regulates Serum Cholesterol, and Stimulates Immunity: An Updated Meta-analysis and Review. In 2016, this meta-analysis of 20 studies observed that “garlic supplements have the potential to lower blood pressure in hypertensive individuals [and] to regulate slightly elevated cholesterol concentrations”.

- A systematic review and metaanalysis on the effects of garlic preparations on blood pressure in individuals with hypertension. In 2015, this meta-analysis of 9 studies observed that “garlic preparations may lower [blood pressure] in hypertensive individuals”.

- Garlic powder intake and cardiovascular risk factors: a meta-analysis of randomized controlled clinical trials. In 2014, this meta-analysis of 22 studies observed that “garlic powder intake reduces the [cardiovascular] risk factors of [total cholesterol], LDL-[cholesterol], [fasting blood glucose] and [blood pressure]”.

- Effect of garlic on serum lipids: an updated meta-analysis. In 2013, this meta-analysis of 38 studies observed that Garlic supplementation may be “effective in reducing total serum cholesterol … and low-density lipoprotein cholesterol”.

This clinical study identifies allicin as the principal bioactive component in Garlic:

- Allicin and allicin-derived garlic compounds increase breath acetone through allyl methyl sulfide: use in measuring allicin bioavailability. In 2005, this study found

that “allyl thiosulfinates (mainly allicin) are solely responsible for breath [allyl methyl sulfide] … a compound which stimulates the production of acetone and which can be used to measure the bioavailability of allicin and, hence, the ability of garlic supplements to represent fresh garlic”.

This clinical study confirms that the bioavailability of allicin in Garlic supplements may be as high as or higher than that of allicin from food sources. It also identifies standardization at 3 to 8 mg allicin daily as the dosage used in most studies, and recommends standardization at 7 to 16 mg allicin daily:

- Allicin Bioavailability and Bioequivalence from Garlic Supplements and Garlic Foods. In 2018, this study found that “bioavailability of allicin from garlic powder supplements containing alliin and active alliinase can be as high as that from an equivalent amount of crushed raw garlic”. It also observed that “almost all clinical trials with garlic powder supplements have used a daily dose standardized at 3.6–7.8 mg allicin potential” and proposed that “the minimum daily dose of a garlic powder supplement for possible health benefits should have high allicin bioavailability … by having an allicin potential of about 7-8 mg … and that the preferred dose for clinical trials should be two times this amount”.

Omega 3 to Support Healthy Triglyceride

Omega 3 Docosahexaenoic Acid and Eicosapentaenoic Acid supplements (dosage between 300 and 4200 mg, standardized at between 180 and 4050 mg EPA and between 120 and 2900 mg DHA, daily) may support healthy triglyceride, according to these clinical studies on humans:

- Fish oil supplementation alters circulating eicosanoid concentrations in young healthy men. In 2013, this study found that Omega 3 supplementation “improved circulating triglyceride levels”. Participants used 3000 mg (2000 mg EPA and 1000 mg DHA) daily for 3 months.

- Effect of fish oil supplementation on serum triglycerides, LDL cholesterol and LDL subfractions in hypertriglyceridemic adults. In 2013, this study found “significant [triglyceride] lowering” with Omega 3 supplementation. Participants

used 4000 mg daily for 12 weeks.

- Effects of omega-3 fatty acids on postprandial triglycerides and monocyte activation. In 2012, this study found that Omega 3 supplementation may “reduce fasting [triglycerides]”. Participants used 4000 mg daily for 3 weeks.

- Docosahexaenoic acid supplementation decreases liver fat content in children with non-alcoholic fatty liver disease: double-blind randomised controlled clinical trial. In 2011, this study found that “triglycerides decreased” with Omega 3 supplementation. Participants used 250 to 500 mg DHA daily for 6 months.

- Moderate doses of EPA and DHA from re-esterified triacylglycerols but not from ethyl-esters lower fasting serum triacylglycerols in statin-treated dyslipidemic subjects: Results from a six month randomized controlled trial. In 2011, this study found that “serum [triglyceride] levels were significantly lowered” with Omega 3 supplementation. Participants used 1680 mg (1010 mg EPA and 670 mg DHA) daily for 6 months.

- Metabolic and endocrine effects of long-chain versus essential omega-3 polyunsaturated fatty acids in polycystic ovary syndrome. In 2011, this study found that Omega 3 supplementation “lowered serum triglyceride”. Participants used 3600 mg (2148 mg EPA and 1452 mg DHA) daily for 6 weeks.

- Dose-response effects of omega-3 fatty acids on triglycerides, inflammation, and endothelial function in healthy persons with moderate hypertriglyceridemia. In 2011, this study found that Omega 3 supplementation “significantly lowered triglycerides”. Participants used 4000 mg (including 1944 mg EPA and 1686 mg DHA) daily for 8 weeks.

- Treatment of rheumatoid arthritis with marine and botanical oils: influence on serum lipids. In 2011, this study found that Omega 3 supplementation “significantly reduced ... triglycerides”. Participants used 3500 mg (2100 mg EPA and 1400 mg DHA) daily for 18 months.

- Effects of prescription omega-3-acid ethyl esters on fasting lipid profile in subjects with primary hypercholesterolemia. In 2011, this study found that, with

Omega 3 supplementation, “significant changes … were observed for … triglycerides”. Participants used 4000 mg daily for 6 weeks.

- Prescription omega-3-acid ethyl esters reduce fasting and postprandial triglycerides and modestly reduce pancreatic β-cell response in subjects with primary hypertriglyceridemia. In 2011, this study found that Omega 3 supplementation “resulted in significant lower mean fasting and postprandial [triglycerides]”. Participants used 1500 to 3000 mg (1100 to 2200 mg EPA and 400 to 800 mg DHA) daily for 6 weeks.

- n-3 LC-PUFA-enriched dairy products are able to reduce cardiovascular risk factors: a double-blind, cross-over study. In 2010, this study found that Omega 3 supplementation “resulted in a significant improvement of [triglycerides]”. Participants used 3000 mg daily for 15 weeks.

- Effect of 6 Weeks of n-3 fatty-acid supplementation on oxidative stress in Judo athletes. In 2010, this study found “significant interaction effect between supplementation and time on triglycerides … with values significantly lower” after Omega 3 supplementation. Participants used 1000 mg (600 mg EPA and 400 mg DHA) daily for 6 weeks.

- The effects of low dose n-3 fatty acids on serum lipid profiles and insulin resistance of the elderly: a randomized controlled clinical trial. In 2010, this study found that Omega 3 supplementation “could significantly protect ... from a rise in serum triglycerides”. Participants used 300 mg (180 mg EPA and 120 mg DHA) daily for 6 months.

- Fish oil supplementation improves endothelial function in normoglycemic offspring of patients with type 2 diabetes. In 2009, this study found that Omega 3 supplementation “decreased plasma triglycerides”. Participants used 2000 mg (including approximately 950 mg EPA and 750 mg DHA) daily for 12 weeks.

- Effect of fish oil (n-3 polyunsaturated fatty acids) on plasma lipids, lipoproteins and inflammatory markers in HIV-infected patients treated with antiretroviral therapy: a randomized, double-blind, placebo-controlled study. In 2009, this study found that Omega 3 supplementation “slightly decreased plasma triglycerides”.

Participants used 1800 mg (including 930 mg EPA and 750 mg DHA) daily for 12 weeks.

- Effects of adding prescription omega-3 acid ethyl esters to simvastatin (20 mg/day) on lipids and lipoprotein particles in men and women with mixed dyslipidemia. In 2008, this study found that, with Omega 3 supplementation, “favorable changes … were also observed for … triglyceride”. Participants used 4000 mg daily for 6 weeks.

- Effects of omega-3 fatty acid supplements on serum lipids, apolipoproteins and malondialdehyde in type 2 diabetes patients. In 2008, this study found that “fasting triglycerides decreased significantly” with Omega 3 supplementation. Participants used 2000 mg daily for 10 weeks.

- Age- and dose-dependent effects of an eicosapentaenoic acid-rich oil on cardiovascular risk factors in healthy male subjects. In 2007, this study found that Omega 3 supplementation “lowered plasma triacylglycerols”. Participants used 1350 to 4050 mg EPA daily for 12 weeks.

- Efficacy and tolerability of adding prescription omega-3 fatty acids 4 g/d to simvastatin 40 mg/d in hypertriglyceridemic patients: an 8-week, randomized, double-blind, placebo-controlled study. In 2007, this study found that Omega 3 supplementation “improved ... lipid and lipoprotein parameters”. Participants used 4000 mg daily for 8 weeks.

- Additive benefits of long-chain n-3 polyunsaturated fatty acids and weight-loss in the management of cardiovascular disease risk in overweight hyperinsulinaemic women. In 2006, this study found “some additional benefits of [Omega 3] on triglycerides”. Participants used 4200 mg (1300 mg EPA and 2900 mg DHA) daily for 24 weeks.

- Microalgal docosahexaenoic acid decreases plasma triacylglycerol in normolipidaemic vegetarians: a randomised trial. In 2006, this study found that Omega 3 “supplementation decreased plasma [triglycerides]”. Participants used 940 mg DHA daily for 8 weeks.

These studies report divergent results:

- Omega-3 fatty acid supplementation improves vascular function and reduces inflammation in obese adolescents. In 2010, this study found “no difference [in] triacylglycerol” but that Omega 3 supplementation “improves vascular function”. Participants used 1200 mg daily for 3 months.

- Acute fish oil and soy isoflavone supplementation increase postprandial serum (n-3) polyunsaturated fatty acids and isoflavones but do not affect triacylglycerols or biomarkers of oxidative stress in overweight and obese hypertriglyceridemic men. In 2009, this study found that “serum [triglycerides] ... did not differ” with Omega 3 supplementation. Participants used 4200 mg (2800 mg EPA and 1400 mg DHA) once.

- Effects of moderate-dose omega-3 fish oil on cardiovascular risk factors and mood after ischemic stroke: a randomized, controlled trial. In 2009, this study found “no effect … of treatment with moderate-dose fish oil supplements on cardiovascular biomarkers”. The study observed that “insufficient dose, short duration of treatment, and/or oxidation of the fish oils may have influenced these outcomes.” Participants used 1200 mg (including 700 mg DHA and 300 mg EPA) daily for 12 weeks.

- Supplementation with omega3 polyunsaturated fatty acids and all-rac alpha-tocopherol alone and in combination failed to exert an anti-inflammatory effect in human volunteers. In 2004, this study found that Omega 3 “supplementation resulted in no changes in plasma lipids”. Participants used 1500 mg daily for 12 weeks.

These clinical study reviews confirm that Omega 3 Docosahexaenoic Acid and Eicosapentaenoic Acid supplements may support healthy triglyceride:

- A meta-analysis shows that docosahexaenoic acid from algal oil reduces serum triglycerides and increases HDL-cholesterol and LDL-cholesterol in persons without coronary heart disease. In 2012, this meta-analysis of 11 studies observed that Omega 3 supplementation “may reduce serum [triglycerides]”.

- Omega-3 fatty acids and hypertriglyceridemia in HIV-infected subjects on antiretroviral therapy: systematic review and meta-analysis. In 2011, this meta-analysis of 4 studies observed that Omega 3 supplements “significantly reduce triglycerides concentrations”.

- Effects of eicosapentaenoic acid versus docosahexaenoic acid on serum lipids: a systematic review and meta-analysis. In 2011, this meta-analysis observed that “both EPA and DHA reduced triglycerides.”

- Benefits of fish oil supplementation in hyperlipidemia: a systematic review and meta-analysis. In 2009, this meta-analysis of 47 studies observed that Omega 3 supplementation “produces a clinically significant dose-dependent reduction of fasting blood [triglycerides]”.

Omega 3 Lysine Complex may be 5 times more bioavailable than traditional fish oil softgels, according to this clinical study:

- In vitro dissolution behaviour and absorption in humans of a novel mixed l-lysine salt formulation of EPA and DHA. In 2020, this study found that bioavailability “was for EPA 5 times higher with [Omega 3 Lysine Complex] than with the [ethyl ester] formulation.”

Garlic and Omega 3 to Support Healthy Heart Function

The combination of Garlic and Omega 3 supplements may support healthy heart function, according to these clinical studies on humans:

- Effect of combined supplementation of fish oil with garlic pearls on the serum lipid profile in hypercholesterolemic subjects. In 2005, this study found that “The co-administration of garlic pearls with fish oil was found to be more effective than placebo.” And “total cholesterol, low-density lipoprotein, serum triglyceride, very low-density lipoprotein, and the total cholesterol: high-density lipoprotein ratio reduced.”

- Modulation of lipid profile by fish oil and garlic combination. In 1997, this study

found that “in addition to the known anticoagulant and antioxidant properties of both fish oil and garlic, the combination causes favorable shifts in the lipid subfractions within 1 month.”

- Effect of garlic and fish-oil supplementation on serum lipid and lipoprotein concentrations in hypercholesterolemic men. In 1997, this study found that “coadministration of garlic with fish oil was well-tolerated and had a beneficial effect on serum lipid and lipoprotein concentrations.” The study also found that “the combination of garlic and fish oil reversed the moderate fish-oil-induced rise in LDL-C.”