# Heartdrops - MONOGRAPH

**Disclaimer:** *These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. Strictly for educational purposes. Not for public distribution.

**HEARTDROPS®**

**1 mL (32 Drops) of Oral Tincture contains:**

**Aged Garlic** (435.5 mg DHE*)
**GCMS verified S-Allyl cysteine** 142 ppm avg
**Cayenne** (2.4 mg DHE* – *Capsicum annuum* fruit)
**Hawthorn Fruit** (35.8 mg DHE* – *Crataegus laevigata*)
**Hawthorn Flower & Leaf** (2.1 mg DHE* – *Crataegus laevigata*)
**Motherwort** (3.1 mg DHE* – *Leonurus cardiaca* herb top) **White Willow** (1.3 mg DHE* – Salix alba stem bark)
**Bilberry** (1.9 mg DHE* – *Vaccinium myrtillus* leaf)
**European Mistletoe** (17.9 mg DHE* – *Viscum album* leaf)

**Non-medicinal ingredients:**
purified water, ethanol USP, natural cinnamon flavour. (Cinnamon **Heartdrops®**)
*DHE = Dry Herb Equivalent

**Dosage:**
Adults, 1 mL (32 drops) – 2.5 mL (80 drops), 3 times daily. May be taken diluted in a small amount of water.

**Indication:**
Helps support a healthy cardiovascular system.

**Detailed Information:**
**Heartdrops®**, an alcohol-based extract of aged garlic, hawthorn fruit, hawthorn leaf & flower, cayenne, European mistletoe leaf and bilberry leaf in combination with motherwort and trace amounts of white willow bark, has been marketed for over 40 years.

In a double-blinded, placebo-controlled, randomised parallel group study to determine if in patients with chronic stable angina using **Heartdrops®** at a dosage below the current minimum dose (15 drops, three times/ day, placed under the tongue and held for a minute) for 12 weeks could reduce selected markers of cardiovascular risk (vascular compliance, exercise tolerance, blood lipid profile, inflammatory markers, blood pressure) and improve quality of life. The reduction in symptom frequency was statistically significant ($p<0.05$) from the 6th to 11th week compared to baseline, while the reduction in symptom severity was significant in weeks 7-8 and 10-12 compared to baseline. The results of this study suggest that supplementation with **Heartdrops®** improved quality of life by reducing the frequency and severity of heart disease symptoms, and without adverse effects or changes in blood chemistry despite patients concurrently taking other heart medications[1].

In a one-year observational study to determine safety and efcacy, fourteen volunteer subjects ingested label recommended dosages of Heartdrops® three times per day while maintaining their usual life-style and habits. Blood pressure was monitored monthly throughout the entire study period, and all 'at risk' blood lipids, including total cholesterol, LDL cholesterol, triglycerides and the total cholesterol/ HDL ratio were calculated using the CardioChek device. Over the one -year study period, the blood lipid values that indicated increased risk to coronary heart disease in the treatment group improved to values that were 'normal' or indicative of reduced risk. The reductions in blood lipid values and diastolic blood pressure were statistically ($P<0.05$) significant. The results of this study supported the safe and efcacious use of **Heartdrops®** as a supplement for people at increased risk of heart disease[2]. Additional actions of **Heartdrops®** suggested by this study included improvement of lipid profiles, as well as in endothelial function and exercise tolerance.

In a single-blind, placebo-controlled study, 150 hyperlipidemic participants were divided randomly into three equal groups and were given either enteric-coated garlic powder tablets (equal to 400 mg garlic, 1 mg allicin) twice daily, anethum graveolens tablets (650 mg) twice daily, or placebo tablets twice daily for 6 weeks. While anethum had no significant efect on lipid profiles, garlic had a statistically ($P<0.001$) significant favourable efect, decreasing total cholesterol and LDL-cholesterol and increasing HDL-cholesterol[3].

Individuals with heart disease often have impaired endothelial function. As a result, vasodilation becomes limited and is worsened by oxidant stress and increased systemic inflammation. In a randomized, placebo-controlled, cross-over study involving 15 men with angiographically-proven coronary artery disease that was being treated with aspirin and a statin, 2-week supplementation (with washout periods) with aged garlic extract (AGE) led to a significant ($P = 0.04$) increase (44%) in brachial artery flow mediated endothelium-dependent dilation (FMD), although circulating markers of oxidative stress (plasma oxidized low density lipoprotein and peroxides), systemic inflammation (plasma C-reactive protein and Individuals with heart disease often have

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However, a recent study investigated whether **AGE** reduces coronary plaque volume measured by cardiac computed tomography angiography (CCTA) in patients with metabolic syndrome (MetS). Fifty-five patients with MetS (mean ± SD age: 58.7 ± 6.7 y; 71% men) were prospectively assigned to consume 2,400 mg **AGE**/day (27 patients) or placebo (28 patients). Both groups underwent CCTA at baseline and follow-up 354 ± 41 days apart. Coronary plaque volume, including total plaque volume (TPV), dense calcium (DC), NCP, and low-attenuation plaque (LAP), were measured based upon predefined intensity cut-of values. Results of multivariable linear regression analysis, adjusting for age, gender, number of risk factors, hyperlipidemia medications, history of coronary artery disease, scan interval time, and baseline %TPV, revealed that the %LAP reduction in the **AGE** group compared with the lack of change in the placebo group was significant (-1.5% ± 2.3% compared with 0.2% ± 2.0%; P = 0.0049). In contrast, no difference was observed in %TPV change (0.3% ± 3.3% compared with 1.6% ± 3.0%, P = 0.13), %NCP change (0.2% ± 3.3% compared with 1.4% ± 2.9%, P = 0.14), or %DC change (0.2% ± 1.4%, compared with 0.2% ± 1.7%, P = 0.99) compared to placebo[9].

Thus, in addition to multiple risk reduction based upon its pleiotropic action profile[6] and a specific anti-arteriosclerotic efect at the molecular level suggested by the garlic-mediated hindrance of membrane calcification[7,8] and/or docking of deleterious lipoproteins to their scavenger receptor[5,9], the use of garlic helps to maintain cardiovascular health and reduce the risk of cardiovascular incidents[5].

**Garlic bulb** at 0.5-12 g/day is Traditionally used in Herbal Medicine to help relieve the symptoms associated with upper respiratory tract infections and catarrhal conditions, as well as to help reduce elevated blood lipid levels/hyperlipidemia and maintain cardiovascular health in adults[10].

**Cayenne fruit** is Traditionally used in Herbal Medicine to help support peripheral circulation when taken at a dry weight equivalent dosage of 15-650 mg/day[11]. Cayenne has long been recognised as one of the most powerful and persistent of cardio-stimulants known, with primary influence on circulation[12], even when only very small amounts are consumed[13].

**Hawthorn fruit** when taken at 0.6-3.5 g/day, and **Hawthorn Leaf & Flower** at 0.5-5 g/day, is used in Herbal Medicine to help maintain and/or support cardiovascular health in adults[14]. Hawthorn has a long-standing reputation as one of the most valuable tonic remedies for the cardiovascular system[15]. While hawthorn fruit has Traditionally been used to strengthen and invigorate the heart and circulatory function[16], leaf & flower preparations have been most studied and shown to possess cardiotonic and coronary vasodilator

properties[17]. When taken in recommended dosages, both types of hawthorn preparation have been indicated for early or mild functional cardiac insufficiency, i.e. Stages I and II according to New York Health Association's classification, as well as for mild forms of arrhythmia and tachycardia[17,18]. The available evidence supports the combination of hawthorn with garlic in **Heartdrops®** for maintenance of cardiovascular health in adults.

**Motherwort** is described in Traditional Herbal Medicine sources as an excellent cardiac tonic, being particularly useful for heart palpitations and cardiac insufciency associated with anxiety and/or nervous conditions[16,19], especially when combined with hawthorn[15], and when taken at a dosage of 2.4-6 g/day[20].

**European mistletoe leaf** preparations are used orally in Traditional Herbal Medicine as cardiotonic and cardioprotective agents with mild hypotensive action[19], [21]. They have been described as particularly helpful in the relief of subjective symptoms associated with cardiovascular deficiencies[19,21], supporting use of the herb as a complimentary and supportive ingredient of **Heartdrops®**.

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Similarly, **Bilberry leaf** preparations are used Traditionally in Herbal Medicine for, among other things, poor circulation and circulatory disorders, functional heart problems, and metabolic stimulation and blood purification[16,19]. Use of bilberry leaf in Traditional Chinese Medicine to raise Central Qi and thereby help in venous insufciency, capillary fragility, and atherosclerosis[22], also supports its use as a complimentary and supportive ingredient of **Heartdrops®.**

**White willow bark**, best known as a natural remedy for relief of fever and pain[16], may mildly potentiate the effects of anticoagulants[23] and may therefore contribute, as a minor ingredient of **Heartdrops®**, to improving blood flow properties helpful in the support and/or maintenance of cardiovascular health.

**Cautions and Warnings:**

Consult a health care practitioner prior to use if you have heart disease, high blood pressure, high cholesterol, anemia, bleeding/clotting disorders, sto® mach ulcer, diabetes, or if you are taking other medications and/or supplements. Consult with a health care practitioner if symptoms persist or worsen.

**Contra-Indications:**

Do not use if you are pregnant or breastfeeding or within 24 hours of surgery.

**Known Adverse Reactions:**

Hypersensitivity/allergic reactions are known to occur; headaches, dizziness, and light-headedness, and thirst may occur, in which case reduce dosage or discontinue use.


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References available upon request. 