

## NPN: 80056684

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

Hawthorn Fruit (317.7 mg DHE\* - Crataegus laevigata) Skullcap (43.1 mg DHE\* - Scutellaria lateriflora aerial parts) Indian Sarsaparilla (38.6 mg DHE\* - Hemidesmus indicus root) Peppermint (35.2 mg DHE\* - Mentha x piperita leaf) Hawthorn Flower & Leaf (31.8 mg DHE\* - Crataegus laevigata) European Mistletoe (31.8 mg DHE\* - Viscum album leaf) Cayenne (2.0 mg DHE\* - Capsicum annuum fruit) \*DHE = Dry Herb Equivalent

### Non-medicinal ingredients:

purified water, ethanol USP, glycerin, spearmint flavour.

#### Directions of Use:

Adults, take 1-3 ml, 3 times daily. Use for at least 2 months to see beneficial results.

#### Indication:

Used in Herbal Medicine to help maintain cardiovascular health in adults.

## **Detailed Information:**

**CardioCalm Drops™** is an hydroethanolic extract of seven (7) herb ingredients, mainly hawthorn fruit, with hawthorn leaf & flower contributing additively to the recommended use of the product to maintain cardiovascular health in adults. The lesser amounts of skullcap, indian sarsaparilla, peppermint, European mistletoe, and cayenne provide supportive and complementary effects when **CardioCalm Drops™** is taken as recommended.

Hawthorn preparations have long been considered among the most valuable tonic remedies for the cardiovascular system<sup>1</sup>. They are used Traditionally to strengthen and invigorate the heart and circulatory function<sup>2</sup>, based on their mildly sedative, analgesic, antispasmodic, antiarrhythmic, diuretic, hypotensive, hypothermic, vasodilatory, and cardiotonic actions<sup>3</sup>. Hawthorn has been indicated for the the refractory period<sup>8</sup>. Randomized, placebo-controlled, double-blind clinical studies have demonstrated hawthorn fruit extracts to be effective in improving exercise tolerance and quality of life in patients with congestive heart failure (NYHA Stage II)<sup>9</sup>. Hawthorn leaf & flower preparations have also been clinically shown to increase exercise capacity in patients with congestive heart failure (NYHA Stagell,10) and with heart failure-related signs and symptoms11, as well as to increase maximum workload and reduce blood pressure/heart rate product concomitant with improving dyspnea and fatigue<sup>12</sup>, and to significantly reduce resting diastolic blood pressure and reduce anxiety<sup>13</sup>. Hawthorn preparations are cost-effective alternatives/adjuncts to chemicalsynthetic drugs for mild forms of arrhythmia and tachycardia, and for early treatment of cardiac insufficiency<sup>14</sup>. On the basis of available evidence, there are no known risks associated with the long-term use of hawthorn<sup>4,5</sup>.

Hawthorn has been indicated for the treatment of NYHA Stage I & II cardiac insufficiency, hypertonic heart, arrhythmia, cerebral insufficiency, mild hypertension, and for support of patients with a history of myocardial infarction<sup>4</sup>. Hawthorn fruit when taken at a dry weight equivalent of 0.6-3.5 g/day, and dried hawthorn leaf & flower at a crude equivalent dosage of 0.5-5 g/day, is used in Herbal Medicine to help maintain and/or support cardiovascular health in adults<sup>5</sup>. Hawthorn preparations have been shown to help dissolve deposits in thickened and sclerotic arteries<sup>6</sup>. Results from preclinical trials have demonstrated hawthorn preparations to also have positive inotropic effects on human heart muscle, to reduce stimulus threshold, and to increase coronary vasodilation<sup>7</sup>. Hawthorn leaf & flower preparations act on the heart by increasing the force of contraction and lengthening the refractory period<sup>8</sup>. Randomized, placebo-controlled, double-blind clinical studies have demonstrated hawthorn fruit extracts to be effective in improving exercise tolerance and quality of life in patients with congestive heart failure (NYHA Stage II)<sup>9</sup>.

**Hawthorn Leaf & Fower** preparations have also been clinically shown to increase exercise capacity in patients with congestive heart failure (NYHA Stage II)<sup>10</sup> and with heart failure-related signs and symptoms<sup>11</sup>, as well as to increase maximum workload and reduce blood pressure/ heart rate product concomitant with improving dyspnea and fatigue<sup>12</sup>, and to significantly reduce resting diastolic blood pressure and reduce anxiety<sup>13</sup>. Hawthorn preparations are cost-effective alternatives/ adjuncts to chemical-synthetic drugs for mild forms of arrhythmia and tachycardia, and for early treatment of cardiac insufficiency<sup>14</sup>. On the basis of available evidence, there are no known risks associated with the long-term use of hawthorn<sup>4.5</sup>.

**Skullcap** is Traditionally used in Herbal Medicine as a mild sedative and sleep aid<sup>15</sup>. It is among the best anxiolytic agents available to herbalists to help strengthen, support and calm the nervous system<sup>16</sup>. One of its main active constituents, the flavone baicalein, has demonstrated cardioprotective effects in numerous in vitro and in vivo animal studies<sup>17</sup>, supporting the Traditional use of skullcap also for functional cardiac disorders attributable to nervous causes, and that are associated with an intermittent pulse<sup>18</sup>. It is considered to be one of the four main ingredients of Traditional herbal formulations for weakness of the heart<sup>16</sup>.

Clinical trials are lacking for **Indian sarsaparilla root**, but it has a long history of use in Ayurvedic Medicine as an alterative tonic and "blood purifier"<sup>19</sup>. While having similar properties to American sarsaparilla (Smilax spp.), including as an anti- inflammatory, its higher content of coumarin may at least partially contribute to its broader use and its "blood purifying" properties.

**Peppermint** is well known for its use in the treatment of various digestive complaints<sup>20</sup>, including to reduce the tone of the gastroesophageal sphincter<sup>21</sup>, making it useful to help reduce or alleviate sympathetic spasms that can manifest as palpitations<sup>1.3</sup>. Peppermint leaf, itself, is a common folk remedy for heart palpitations<sup>22</sup>, circulatory problems, heart muscle weakness, and heart disturbances attributable to intestinal gas, dyspepsia and/or indigestion<sup>3</sup>.

**European mistletoe leaf** preparations are used orally in Traditional Herbal Medicine as cardiotonic and cardioprotective agents with mild hypotensive action<sup>23</sup>. They have been described as particularly helpful in the relief of subjective symptoms associated with cardiovascular deficiencies, for which there is early clinical support<sup>24</sup>.

**Cayenne** is well known for its stimulant and counterirritant effects and has long been recognised as one of the most powerful and persistent of cardio-stimulants known, with a primary influence on circulation<sup>25</sup>, even when only very small amounts are consumed<sup>26</sup>. It is used Traditionally in Herbal Medicine to help support peripheral circulation when taken at a dry weight equivalent dosage of 15-650 mg/day<sup>27</sup>. It's main active constituent, capsaicin, has also been shown to increase the permeability of epithelial cells of the gastrointestinal tract to ions and macromolecules<sup>28</sup>, thereby facilitating the absorption of medicinal agents with which it is co-administered.

The specific combination of herbal extract ingredients making up the **CardioCalm Drops™** formulation is unique, and provides a safe, gentle and effective product for its licensed use as a Natural and Non-prescription Health Product to help maintain cardiovascular health in adults.



#### **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, stomach ulcer or gallstones, or if you are taking other medications and/or supplements. Consult a health care practitioner if symptoms persist or worsen.

## **Contra-Indications:**

Do not take if you are pregnant or breastfeeding. Consumption with alcohol, other drugs and/or natural health products with sedative properties is not recommended.

#### **Known Adverse Reactions:**

Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness. Hypersensitivity/allergic reactions are known to occur; headaches, dizziness, and light-headedness, and thirst may occur, in which case discontinue use.





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