

SUMMARY OF CLINICAL STUDIES

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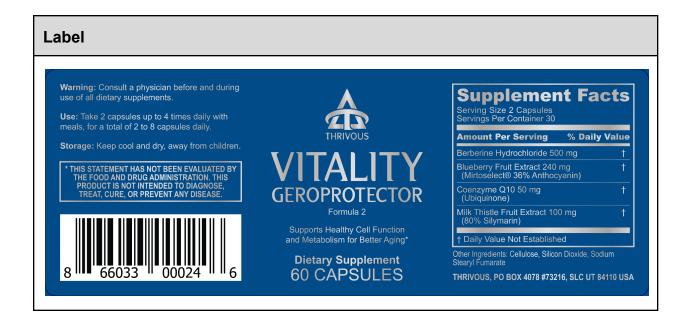


Table of Contents

Berberine to Support Healthy Blood Sugar and Metabolic Function	2
Blueberry to Support Healthy DNA and Genetic Function	4
Coenzyme Q10 to Support Healthy Mitochondria and Cellular Function	6

Berberine to Support Healthy Blood Sugar and Metabolic Function

Berberine supplements (one to three doses of 500 mg daily) may support healthy blood sugar levels and metabolic function, according to these clinical studies on humans:

- Efficacy of Berberine in Patients with Non-Alcoholic Fatty Liver Disease. In 2015, this study found that, "as compared with [lifestyle intervention], [Berberine] treatment plus [lifestyle intervention] resulted in a significant reduction of [hepatic fat content] ... paralleled with better improvement in body weight, [insulin resistance], and serum lipid profiles". Participants used three doses of 500 mg for a total of 1500 mg daily for 16 weeks.
- Effect of berberine administration on metabolic syndrome, insulin sensitivity, and insulin secretion. In 2013, this study found that "administration of berberine leads to remission of metabolic syndrome and decreases in waist circumference, [systolic blood pressure], triglycerides, and total insulin secretion, with an increase in insulin sensitivity". Participants used three doses of 500 mg for a total of 1500 mg daily for 3 months.
- Treatment of type 2 diabetes and dyslipidemia with the natural plant alkaloid berberine. In 2008, this study found that "fasting and postload plasma glucose decreased" with Berberine supplementation. Participants used two doses of 500 mg for a total of 1000 mg daily for 3 months.
- Efficacy of berberine in patients with type 2 diabetes mellitus. In 2008, this study
 found that "the hypoglycemic effect of berberine was similar to that of metformin,"
 and "berberine is a potent oral hypoglycemic agent with beneficial effects on lipid
 metabolism." 84 participants used Metformin or three doses of 500 mg Berberine

for a total of 1500 mg daily for three months.

This clinical study review confirms that Berberine supplements may support healthy blood sugar levels and metabolic function:

Berberine in the treatment of type 2 diabetes mellitus: a systemic review and meta-analysis. In 2012, this review of 14 studies found that "compared with lifestyle modification with or without placebo, the cointervention of berberine and lifestyle modification showed significantly hypoglycaemic and antidyslipidemic response". Participants generally used one to three doses of 500 mg for a total of 500 to 1500 mg daily for 8 to 24 weeks.

These clinical studies indicate that Milk Thistle supplements (in a 1:5 ratio with Berberine) may increase the efficacy of Berberine:

- Bioimpedance analysis, metabolic effects and safety of the association Berberis aristata/Bilybum marianum: a 52-week double-blind, placebo-controlled study in obese patients with type 2 diabetes. In 2017, this study found that fasting blood glucose and insulin, insulin resistance, cholesterol, triglycerides, uric acid, BMI, waist circumference, and waist-to-hip ratio "had significantly improved in the [Berberine]-treated group" and it also found "a significant uric acid lowering activity as an additive beneficial effect of the association" of Berberine and Milk Thistle.
- The role of a fixed Berberis aristata/Silybum marianum combination in the treatment of type 1 diabetes mellitus. In 2016, this study found "a decrease of [fasting plasma glucose], and [post-prandial glucose] ... a decrease of total cholesterol, triglycerides, and LDL-cholesterol and an increase of HDL-cholesterol" with Berberine and Milk Thistle supplementation. Participants used two doses of approximately 500 mg Berberine and 100 mg Milk Thistle for a total of approximately 1000 mg Berberine and 200 mg Milk Thistle daily for 6 months.
- Berberis aristata combined with Silybum marianum on lipid profile in patients not tolerating statins at high doses. In 2015, this study found that Berberine and Milk Thistle "reduced fasting plasma glucose ... [and] insulin". Participants used two

- doses of approximately 500 mg Berberine and 100 mg Milk Thistle for a total of approximately 1000 mg Berberine and 200 mg Milk Thistle daily for 6 months.
- Berberis aristata/Silybum marianum fixed combination (Berberol(®)) effects on lipid profile in dyslipidemic patients intolerant to statins at high dosages: a randomized, placebo-controlled, clinical trial. In 2015, this study found that "fasting plasma glucose, insulin ... levels were reduced by" Berberine and Milk Thistle. Participants used two doses of approximately 500 mg Berberine and 100 mg Milk Thistle for a total of approximately 1000 mg Berberine and 200 mg Milk Thistle daily for 6 months.
- Effects of Berberis aristata/Silybum marianum association on metabolic parameters and adipocytokines in overweight dyslipidemic patients. In 2013, this study found that the Berberine and Milk Thistle "combination seems to be safe and effective in improving lipid profile, but also in improving insulin resistance and adipocytokines levels". Participants used two doses of approximately 500 mg Berberine and 100 mg Milk Thistle for a total of approximately 1000 mg Berberine and 200 mg Milk Thistle daily for 3 months.
- Pilot study on the additive effects of berberine and oral type 2 diabetes agents for patients with suboptimal glycemic control. In 2012, this study found that the combination of Berberine and Milk Thistle "had a positive effect on glycemic and lipid parameters, significantly reducing glycosylated hemoglobin, basal insulin, homeostatic model assessment of insulin resistance, total and low-density lipoprotein cholesterol, and triglycerides". Participants used two doses of approximately 500 mg Berberine and 100 mg Milk Thistle for a total of approximately 1000 mg Berberine and 200 mg Milk Thistle daily for 90 days.

Blueberry Anthocyanin to Support Healthy DNA and Genetic Function

Blueberry Anthocyanin supplements (dosage at 350 to 1400 mg Anthocyanin daily) may support healthy DNA and genetic function, according to these clinical studies on humans:

• Effect Of A Wild Blueberry (Vaccinium Angustifolium) Drink Intervention On

Markers Of Oxidative Stress, Inflammation And Endothelial Function In Humans With Cardiovascular Risk Factors. In 2013, this study found that Blueberry "significantly reduced the levels of oxidized DNA bases and increased the resistance to oxidatively induced DNA damage". Participants used 25 g (375 mg Anthocyanin) daily for 6 weeks.

- Modulation of Nrf2-dependent gene transcription by bilberry anthocyanins in vivo.
 In 2013, this study found that acute Blueberry supplementation provided a "decrease in oxidative DNA damage".
- A Single Portion Of Blueberry (Vaccinium Corymbosum L) Improves Protection
 Against DNA Damage But Not Vascular Function In Healthy Male Volunteers. In
 2013, this study found that Blueberries "improve cell antioxidant defense against
 DNA damage". Participants used 300 g (348 mg Anthocyanin) acutely.
- Consumption Of Blueberries With A High-carbohydrate, Low-fat Breakfast
 Decreases Postprandial Serum Markers Of Oxidation. In 2013, this study found
 that Blueberry "can provide statistically significant oxidative protection".
 Participants used 75 g (968 mg Anthocyanin) daily for 3 weeks.
- <u>Bilberries reduce low-grade inflammation in individuals with features of metabolic syndrome.</u> In 2012, this study found that Blueberry "consumption may reduce low-grade inflammation". Participants used 400 g (1381 mg Anthocyanin) daily for 2 months.
- Effect Of New Zealand Blueberry Consumption On Recovery From Eccentric
 Exercise-induced Muscle Damage. In 2012, this study found that Blueberry
 "accelerates recovery of muscle peak isometric strength ... [and] appears to
 involve an up-regulation of adaptive processes, i.e. endogenous antioxidant
 processes". Participants used 1000 g (483 mg Anthocyanin) acutely.
- Effect Of Blueberry Ingestion On Natural Killer Cell Counts, Oxidative Stress, And Inflammation Prior To And After 2.5 H Of Running. In 2011, this study found that Blueberry "increases [natural killer] cell counts, and acute ingestion reduces oxidative stress and increases anti-inflammatory cytokines". Participants used 250 g daily for 6 weeks.

- Impact Of Multiple Genetic Polymorphisms On Effects Of A 4-week Blueberry
 Juice Intervention On Ex Vivo Induced Lymphocytic DNA Damage In Human
 Volunteers. In 2007, this study found that Blueberry provided "20% protection ...
 against ... oxidative DNA damage". Participants used 1000 ml daily for 4 weeks.
- The Effect Of Wild Blueberry (Vaccinium Angustifolium) Consumption On Postprandial Serum Antioxidant Status In Human Subjects. In 2002, this study found that Blueberry "is associated with a diet-induced increase in ex vivo serum antioxidant status". Participants used 100 g (1200 mg Anthocyanin) acutely.

Mirtoselect® evidences four times greater bioavailability than common Blueberry Anthocyanin extract, according to this clinical study:

 The effect of a natural, standardized bilberry extract (Mirtoselect®) in dry eye: a randomized, double blinded, placebo-controlled trial. In 2017, this study found that "relative bioavailability of Mirtoselect® compared to the highly purified anthocyanins-rich fraction, expressed as the ratio of the dosage adjusted-AUC values, resulted 4."

Coenzyme Q10 to Support Healthy Mitochondria and Cellular Function

Coenzyme Q10 supplements (dosage at 100 to 300 mg daily) may support healthy mitochondria and cellular function, according to these clinical studies on humans:

- Can coenzyme q10 improve clinical and molecular parameters in fibromyalgia?
 In 2013, this study found that Coenzyme Q10 supplementation resulted in "recovery of inflammation, antioxidant enzymes, mitochondrial biogenesis, and AMPK gene expression levels". Participants used 300 mg daily for 40 days.
- Increased oxidative stress and coenzyme Q10 deficiency in juvenile fibromyalgia: amelioration of hypercholesterolemia and fatigue by ubiquinol-10 supplementation. In 2013, this study found that Coenzyme Q10 supplementation "improved chronic fatigue". Participants used 100 mg daily for 12 weeks.

- Oxidative stress correlates with headache symptoms in fibromyalgia: coenzyme
 Q₁₀ effect on clinical improvement. In 2012, this study found that Coenzyme Q10
 "restored biochemical parameters [related to oxidative stress and bioenergetic
 status in blood mononuclear cells] and induced a significant improvement in
 clinical and headache symptoms". Participants used three doses of 100 mg for a
 total of 300 mg daily for 3 months.
- Oral coenzyme Q10 supplementation improves clinical symptoms and recovers pathologic alterations in blood mononuclear cells in a fibromyalgia patient. In 2012, this study found that, "at the cellular level, CoQ10 treatment restored mitochondrial dysfunction and the mtDNA copy number, decreased oxidative stress, and increased mitochondrial biogenesis".
- Coenzyme Q10 improves seminal oxidative defense but does not affect on semen parameters in idiopathic oligoasthenoteratozoospermia: a randomized double-blind, placebo controlled trial. In 2011, this study found that Coenzyme Q10 supplementation "is associated with alleviating oxidative stress". Participants used 200 mg daily for 12 weeks.
- Reversal of mitochondrial dysfunction by coenzyme Q10 supplement improves endothelial function in patients with ischaemic left ventricular systolic dysfunction: a randomized controlled trial. In 2011, this study found that Coenzyme Q10 supplementation "improved mitochondrial function". Participants used 300 mg daily for 8 weeks.
- Effects of coenzyme Q10 supplementation on liver mitochondrial function and aerobic capacity in adolescent athletes. In 2007, this study found that Coenzyme Q10 supplementation "can depress lipid peroxidation". Participants used 100 mg daily for 1 month.