

# Florasterol™

In depth product information

June, 2009

Florasterol™ provides a unique combination of natural compounds known to help maintain normal cholesterol levels. It is not intended as a replacement for any pharmaceutical drug, nor is any material in this data sheet intended as medical advice. As with all health conditions, those with elevated cholesterol are advised to seek professional medical care.

## **Stanols/Sterols**

[Requirements/Sources](#) | [Therapeutic Dosages](#) | [Therapeutic Uses](#) | [What Is the Scientific Evidence for Stanols?](#) | [Safety Issues](#) | [References](#)

### **Supplement Forms/Alternate Names**

- Phytosterols; Sitostanol; Campestanol; Stigmastanol; 5-Alpha-Stanols; Stanol esters; Sterols; Sterol esters; Phytosterols

### **Principal Proposed Uses**

- [Lowering Cholesterol](#)

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Stanols are substances that occur naturally in various plants. Their cholesterol-lowering effects were first observed in animals in the 1950s. Since then, a substantial amount of research suggests that plant stanols (usually modified into stanol esters) can help to lower cholesterol in individuals with normal or mildly to moderately elevated levels. Stanols are available in margarine spreads, salad dressings, and dietary supplement tablets.

Related substances called sterols or phytosterols (such as beta-sitosterol) and sterol esters appear to lower cholesterol in much the same manner as stanols. [9,20,22,54,55,57-60](#)

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### **Requirements/Sources**

Sterols are found in most plant foods. Stanols occur naturally in wood pulp, tall oil (a by-product of paper manufacturing), and soybean oil, and can also be manufactured from the sterols found in many foods. Stanol and sterol esters are manufactured by processing stanols or sterols with

fatty acids from vegetable oils.<sup>3</sup> Stanol/sterols and their esters are added to margarine spreads and salad dressings and are also available as dietary supplement tablets.

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## Therapeutic Dosages

Typical dosages of stanol/sterols and their esters to improve cholesterol profile range from 2.7 to 5.1 g per day.<sup>4,74</sup> One study suggests that using stanol products once a day may be as effective as dividing up your intake throughout the day.<sup>5</sup> It may take up to 3 months to show a substantial decrease in total cholesterol values.<sup>6</sup>

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## Therapeutic Uses

Strong evidence tells us that stanol/sterols and their ester forms can significantly improve [cholesterol](#) profile [7-20.36.54-56.58-67.70.74.75](#)

There are no other known medicinal uses of stanols or stanol esters. Phytosterols do offer additional potential benefits, but these are discussed in the [Beta-sitosterol](#) article.

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## What Is the Scientific Evidence for Stanols/Sterols?

Because they are structurally similar to cholesterol, stanols (and sterols) can displace cholesterol from the "packages" that deliver cholesterol for absorption from the intestines to the bloodstream.<sup>22</sup> This displaced cholesterol is then excreted from the body. This action not only interferes with the absorption of cholesterol from food, it has the additional (and probably more important) effect of removing cholesterol from substances made in the liver that are recycled through the digestive tract.

Numerous [double-blind, placebo-controlled](#) studies, ranging in length from 30 days to 12 months and involving a total of more than 1,000 people, have found that stanol/sterols and their esters are effective for improving cholesterol profile. [17.23-36.54-56.58-67.70.71.74-77](#) The combined results suggest that these substances can reduce total cholesterol and LDL ("bad") cholesterol by about 10% to 15%. They do not, however, have much of an effect on HDL ("good") cholesterol, nor on triglycerides.

For example, in a double-blind, placebo-controlled study, 153 people with mildly elevated cholesterol were given sitostanol esters in margarine (at 1.8 or 2.6 g of sitostanol per day), or margarine without sitostanol ester, for a total of one year.<sup>39</sup> The results in the treated group receiving 2.6 g per day showed improvements in total cholesterol by 10.2% and LDL cholesterol

by 14.1%—significantly better than the results in the control group. Neither triglycerides nor HDL cholesterol levels were affected.

[Fish oil](#) too has been shown to have a favorable effect on fats in the blood, in particular triglycerides. A study investigating the possible benefit of combining sterols with fish oil found that together they significantly lowered total cholesterol, LDL-cholesterol, and triglycerides, and raised HDL-cholesterol in subjects with undesirable cholesterol profiles.<sup>78</sup>

Even people already taking standard medications to improve cholesterol profile (specifically, drugs in the statin family) appear to benefit when they additionally use stanols/sterols.<sup>42,43,57,73,75</sup> According to one study, if you are on statins and start taking sterol ester margarine as well, your cholesterol will improve to the same effect as if you doubled the statin dose.<sup>57</sup>

Stanols or sterols also appear to be safe and effective for improving cholesterol profile in people with type 2 (adult-onset) [diabetes](#).<sup>40,41,62</sup>

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## Safety Issues

Sterols are presumed safe because they are found in many foods. Stanols are also considered safe, but for a different reason: they are not absorbed.<sup>44,45,68</sup> No adverse effects have been reported in any of the studies on lowering cholesterol, with the exception of one study that reported mild gastrointestinal complaints in a few preschool children.<sup>46</sup> In addition, no toxic signs were observed in rats given stanol esters for 13 weeks at levels comparable to or exceeding those recommended for lowering cholesterol.<sup>47</sup>

Although concerns have been expressed that stanol esters might impair absorption of the fat-soluble vitamins [A](#), [D](#), and [E](#), this does not seem to occur at the dosages required to lower cholesterol.<sup>48</sup> Stanol esters might interfere with absorption of alpha- and [beta-carotene](#),<sup>49,50,53</sup> although some studies have found no such effect.<sup>51,52</sup> Evidence is also conflicting whether sterols or sterol esters impair nutrient absorption.<sup>69,72</sup> Until more is learned, it may be reasonable for people using stanol or sterol products to take a [multivitamin/multimineral tablet](#).

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## **Guggul**

[What Is Guggul Used for Today?](#) | [What Is the Scientific Evidence for Guggul?](#) | [Dosage](#) | [Safety Issues](#) | [References](#)

*Commiphora mukul*

### **Principal Proposed Uses**

- [High Cholesterol](#)

### **Other Proposed Uses**

- [Acne](#); [Diabetes](#); [Weight Loss](#)

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Guggul, the sticky gum resin from the mukul myrrh tree, plays a major role in [Ayurveda](#), the traditional herbal medicine of India. It was traditionally combined with other herbs for the

treatment of arthritis, skin diseases, pains in the nervous system, obesity, digestive problems, infections in the mouth, and menstrual problems.

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## What Is Guggul Used for Today?

Based on preliminary studies, guggul has become a popular herbal treatment for [high cholesterol](#).<sup>2-5</sup> However, the best-designed trial failed to find benefit.

Other potential uses of guggul have no more than minimal supporting evidence. One small study hints that guggul might be helpful for [acne](#).<sup>6</sup> In addition, a study in mice found potential [anti-diabetic](#) effects.<sup>7</sup>

Recently, guggul has been promoted as a [weight-loss](#) agent. Supposedly, it works by enhancing thyroid function. However, there is little evidence that guggul actually affects the thyroid, and one small [double-blind, placebo-controlled](#) trial failed to find it effective for weight loss.<sup>8</sup>

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## What Is the Scientific Evidence for Guggul?

### High Cholesterol

Three [double-blind](#) studies performed in India found evidence that guggul can reduce [cholesterol](#) levels. However, the largest placebo-controlled study failed to find benefit.

One of the positive placebo-controlled studies enrolled 61 individuals and followed them for 24 weeks.<sup>9</sup> After 12 weeks of following a healthy diet, half the participants received placebo and the other half received guggul at a dose providing 100 mg of guggulsterones daily. The results after 24 weeks of treatment showed that the treated group experienced an 11.7% decrease in total cholesterol, along with a 12.7% decrease in LDL ("bad" cholesterol), a 12% decrease in triglycerides, and an 11.1% decrease in the total cholesterol/HDL ("good" cholesterol) ratio. These improvements were significantly greater than what was seen in the placebo group.

Similar results were seen in a double-blind, placebo-controlled trial of 40 individuals.<sup>10</sup>

A double-blind study of 228 individuals given either guggul or the standard drug clofibrate found approximately equal efficacy between the two treatments.<sup>11</sup> However, the absence of a placebo group makes these results less than reliable.

In contrast to these results, a double-blind, placebo-controlled study of 103 people failed to find guggul effective at a dose of 75 mg or 150 mg of guggulsterones daily.<sup>15</sup> In fact, the herb seemed to worsen levels of LDL ("bad") cholesterol. The reason for this discrepancy is not clear.

## Acne

A small controlled trial compared oral gugulipid (50 mg of guggulsterones twice daily) against tetracycline for the treatment of [acne](#) and reported equivalent results.<sup>6</sup> Unfortunately, the study report does not state whether this trial was double-blind, and it also lacked a placebo group. (For information on why this matters, see [Why Does This Database Rely on Double-blind Studies?](#))

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## Dosage

Guggul is manufactured in a standardized form that provides a fixed amount of guggulsterones, the presumed active ingredients in guggul. The typical daily dose should provide 100 mg of guggulsterones.

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## Safety Issues

In clinical trials of standardized guggul extract, no significant side effects other than occasional mild gastrointestinal distress or allergic skin rashes have been seen.<sup>12,13-15</sup> Lab tests done in the course of these trials did not reveal any alterations in liver or kidney function, blood cell numbers and appearance, heart function, or blood chemistry.

Drugs in the [statin family](#) used to reduce cholesterol can cause a potentially serious condition called rhabdomyolysis, in which muscle fibers break down. One case report hints that this could occur with guggul, as well.<sup>16</sup>

Safety in young children, pregnant or nursing women, or those with severe liver or kidney disease has not been established.

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## **Artichoke**

[What Is Artichoke Used for Today?](#) | [What Is the Scientific Evidence for Artichoke?](#) | [Dosage](#) | [Safety Issues](#) | [References](#)

*Cynara scolymus*

### **Principal Proposed Uses**

- [High Cholesterol](#); [Dyspepsia \(Indigestion\)](#)

### **Other Proposed Uses**

- [Liver Protection](#)

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The artichoke is one of the oldest cultivated plants.<sup>1</sup> It was first grown in Ethiopia and then made its way to southern Europe via Egypt. Its image is found on ancient Egyptian tablets and sacrificial altars. The ancient Greeks and Romans considered it a valuable digestive aid and reserved what was then a rare plant for consumption in elite circles. In sixteenth-century Europe, the artichoke was also considered a "noble" vegetable meant for consumption by the royal and the rich.

In traditional European medicine, the leaves of the artichoke (not the flower buds, which are the parts commonly cooked and eaten as a vegetable) were used as a diuretic to stimulate the kidneys and as a "choleric" to stimulate the flow of bile from the liver and gallbladder. (Bile is a yellowish-brown fluid manufactured in the liver and stored in the gallbladder; it consists of numerous substances, including several that play a significant role in digestion.)

In the first half of the twentieth century, French scientists began modern research into these traditional medicinal uses of the artichoke plant.<sup>1</sup> Their work suggested that the plant does indeed stimulate the kidney and gallbladder. Mid-century, Italian scientists isolated a compound from artichoke leaf called cynarin, which appeared to duplicate many of the effects of whole artichoke. Synthetic cynarin preparations were used as a drug to stimulate the liver and gallbladder and to treat elevated cholesterol from the 1950s to the 1980s; competition from newer pharmaceuticals has since eclipsed the use of cynarin.

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### **What Is Artichoke Used for Today?**

Artichoke leaf (as opposed to cynarin) continues to be used in many countries.

[Germany's Commission E](#) has authorized its use for "dyspeptic problems."<sup>2</sup> [Dyspepsia](#) is a rather vague term that corresponds to the common word "indigestion," indicating a variety of digestive problems including discomfort in the stomach, bloating, lack of appetite, nausea, and mild diarrhea or constipation. At least one substantial double-blind study indicates that artichoke leaf is indeed helpful for this condition.<sup>13</sup>

Another fairly substantial study indicates that artichoke leaf may help lower [cholesterol](#).<sup>7</sup>

Based on a general notion that artichoke leaf is good for the liver, it has become a popular treatment for alcohol-induced hangovers. However, a small double-blind, placebo-controlled study failed to find it more effective than placebo.<sup>12</sup>

A number of [animal](#) studies suggest that artichoke protects the [liver](#) from damage by chemical toxins.<sup>8</sup> Artichoke's liver-protective effects, however, have never been proven in controlled clinical trials.

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## What Is the Scientific Evidence for Artichoke?

### High Cholesterol

In a [double-blind, placebo-controlled study](#) of 143 people with [high cholesterol](#), artichoke leaf extract significantly improved cholesterol readings.<sup>9</sup> Total cholesterol fell by 18.5% as compared to 8.6% in the placebo group; LDL cholesterol by 23% vs. 6%; and LDL-to-HDL ratios by 20% vs. 7%. In a subsequent study of 75 otherwise healthy people with high cholesterol, artichoke leaf extract significantly reduced total cholesterol compared to placebo, but it did not affect LDL, HDL, or triglycerides levels.<sup>14</sup>

Another placebo-controlled study of 44 healthy people failed to find any improvement in cholesterol levels attributable to artichoke leaf.<sup>10</sup> The researchers note, however, that study participants, on average, started the trial with lower-than-normal cholesterol levels (due to a statistical accident); improvement, therefore, couldn't be expected!

Artichoke leaf may work by interfering with cholesterol synthesis.<sup>10</sup> Besides cynarin, a compound in artichoke called luteolin may play a role in reducing cholesterol.<sup>11</sup>

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### Dyspepsia

In Europe, vague digestive symptoms are commonly attributed to inadequate flow of bile from the gallbladder. Evidence tells us that artichoke leaf does indeed stimulate the gallbladder.<sup>3,4,5</sup> This by itself does not prove artichoke helpful for dyspepsia. In 2003, however, a large (247 participant) double-blind study evaluated artichoke leaf as a treatment for dyspepsia.<sup>13</sup> In this carefully conducted study, artichoke leaf extract proved significantly more effective than placebo for alleviating digestive symptoms.

A previous study of an herbal combination containing artichoke leaf also found benefits.<sup>6</sup>

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### Dosage

[Germany's Commission E](#) recommends 6 g of the dried herb or its equivalent per day, usually divided into 3 doses. Artichoke leaf extracts should be taken according to label instructions.

**Warning:** People with gallbladder disease should use artichoke only under medical supervision (see Safety Issues below).

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## Safety Issues

Artichoke leaf has not been associated with significant side effects in studies so far, but full safety testing has not been completed. For this reason, it should not be used by pregnant or nursing women. Safety in young children or in people with severe liver or kidney disease has also not been established.

In addition, because artichoke leaf is believed to stimulate gallbladder contraction, individuals with [gallstones](#) or other forms of gallbladder disease could be put at risk by using this herb. Such individuals should use artichoke leaf only under the supervision of a physician. It is possible that increased gallbladder contraction could lead to obstruction of ducts or even rupture of the gallbladder.

Finally, individuals with known allergies to artichokes or related plants in the *Asteraceae* family, such as arnica or chrysanthemums, should avoid using artichoke or cynarin preparations.

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## **Maitake**

[What Is Maitake Used for Today?](#) | [Dosage](#) | [Safety Issues](#) | [References](#)

*Grifola frondosa*

### **Principal Proposed Uses**

- [Adaptogen \(Improve Resistance to Stress\)](#); [Strengthen Immunity](#)

## Other Proposed Uses

- [Diabetes](#); [Cancer Treatment](#); [HIV Support](#); [High Cholesterol](#); [Hypertension \(High Blood Pressure\)](#)

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Maitake is a medicinal mushroom used in Japan as a general promoter of robust health. As with [Coriolus versicolor](#), [shiitake](#), and [reishi](#) (all fungi), innumerable healing powers have been attributed to maitake, ranging from curing cancer to preventing heart disease. Unfortunately, there hasn't been enough reliable research yet to determine whether any of these ancient beliefs are really true.

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## What Is Maitake Used for Today?

Contemporary herbalists classify maitake as an adaptogen, a substance said to help the body adapt to [stress](#) and resist infection (see the article on [Ginseng](#) for further explanation about adaptogens). However, we lack definitive scientific evidence to show us that maitake (or any other purported adaptogen) really functions in this way.

Most investigation has focused on the polysaccharide constituents of maitake. This family of substances is known to affect the human immune system in complex ways, and one in particular, beta-D-glucan, has been studied for its potential benefit in treating [cancer](#) and [HIV](#).<sup>1,2</sup> Highly preliminary studies also suggest that maitake may be useful in treating [diabetes](#), [hypertension](#) (high blood pressure), and [high cholesterol](#).<sup>3,4</sup> However, there is no real evidence as yet that maitake is effective for these or any other illnesses.

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## Dosage

Maitake is an edible mushroom that can be eaten as food or made into tea. A typical dosage of dried maitake in capsule or tablet form is 3 to 7 g daily.

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## Safety Issues

Maitake is widely believed to be safe, although formal safety studies have not been performed. Safety in young children, pregnant or nursing women, or those with severe liver or kidney disease has not been established.

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