Moducare™ and the immune system

The topic of immune support for FIP cats often comes up. The accepted immune booster of L-lysine, although reputed appropriate for herpesvirus, is not recommended for cats with FIP. L-Lysine interferes with arginine intake, an essential amino-acid. Also, recent publications and research are questioning the claims that Lysine is effective at all. However, one often forgotten supplement that has been formulated for use both for humans and animals alike is Moducare™.

Moducare™ is the only clinically tested plant sterol/sterolin product that has been found to be effective in modulating the immune system. Research into Moducare™, one of the Essential Sterolin Products (EPI), has been effective since the 1980s. What sets Moducare™ aside is that numerous research studies on sterolins and sterols, including placebo-controlled, double-blind studies, have been published in international medical journals and attracted attention worldwide. Moducare™ is a unique, patented blend of plant sterols and sterolins that have been extensively researched for their powerful immune regulating effects and is an affordable and effective treatment that keeps natural resistance functioning optimally.

The plant sterols and sterolins in Moducare™ help promote a balanced immune system. How does it exactly work? To understand this we need to look into how plant sterols and sterolins function. “Plant sterols – phytosterols and their glycosides (also known as phytosterolins) – are fats that are present in fruits, vegetables, and medicinal plants. Beta-sitosterol (BSS) and its glycoside (BSSG) are the most abundant of these plant sterols. BSS and BSSG, even at very low levels, have been shown to enhance the activity of various cells in the body recognized as having positive immune system activity”. Moducare™ works to enhance immunity on a cellular level and down-regulates an overactive immune response. It is an immune regulator, so it works where and how the body needs it to.

To understand how best Moducare™ can be used, consider some questions that are often raised.

What are sterols and sterolins?
Sterol is a plant fat found in all plant-based foods. Sterolin is its glucoside, a molecular structure joined to the sterol. Sterolin is easily destroyed, and without it, the sterol does not have the same immune-enhancing benefits. Moducare™ uses a proprietary process to preserve the ideal combination of sterols and sterolins.

Is there any research behind this product?
Research on sterols has been underway since the 1920s, and Professor Bouic and Dr Johan

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Lamprecht (see the research paper below this) have been researching the exact combination of sterols and sterolins found in Moducare™ for over a decade. The work of Professor Bouic and his team, and others have been published in prestigious, peer-reviewed international journals.

**Why is the "sterolin" such an important part of the Moducare™ formulation?**
In nature, plants never contain sterols only. The sterols are always associated with their glucoside "sterolin" (a glucose molecule attached to the sterol molecule). Research has shown quite clearly that the blend of sterols/sterolins in a 100:1 ratio exhibits the best immunomodulatory activity.

**Are there any side effects?**
Long-term studies involving 25,000 humans found no significant side effects. In addition, standard toxicology studies, pre-clinical testing and clinical observations have found no adverse effects.

**Are there any contraindications?**
Recipients of foreign organs and tissues, including bone marrow and corneal transplants, are cautioned not to take any immune regulating nutritional supplements. Therefore, sterols and sterolins are NOT recommended for transplant patients. People with synthetic replacement/reconstruction will not be affected, eg. hip, knee, breast, pacemaker.
Diabetics should monitor their blood sugar closely as many have experienced a reduction in insulin requirements. They should start with one capsule daily to ensure a gradual increase in sterols and sterolins. This data can be extrapolated to include cats being treated with Moducare. Care should be exercised if your cat is diabetic and continuous ongoing assessment needs to be done.

**Can Moducare™ be given with other medication or other supplements?**
There are no known interactions with Moducare™ and any prescribed medication or natural supplement. However, concurrent treatment with Moducare and Polyprenyl Immunostimulant is advocated against as these will work in opposition to each each other.

**What about allergic reactions?**
An allergic reaction is extremely unlikely, as Moducare™ contains no artificial colouring, preservatives, sweeteners or salicylates. It also contains no soy, sugar, acacia, barley, wheat, corn, millet, dairy, lactose, yeast, gluten or other common allergens.

**Are sterols the same as steroids?**
Sterols, including cholesterol, are in the same large classification family of steroids but they do not have the negative effects that are often associated with steroids. Every member of the steroid family has a different activity and only a few have negative effects.

**Is Moducare™ an immune "booster" like echinacea (or Polyprenyl Immunostimulant)?**
The key difference between Echinacea, Polyprenyl Immunostimulant, and Moducare™ is that Echinacea and PI stimulate/boost the immune system, while Moducare™ balances it. Echinacea, Polyprenyl Immunostimulant or any other immune stimulant is not recommended for prolonged use (PI

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for FIP is excluded from this statement), or for use with autoimmune conditions. Moducare™ allows
the immune system to regulate itself: "upregulating" or boosting an underactive response and
"downregulating" an overactive one.

**Should Moducare™ be taken for a few months and once the immune system is balanced, stop taking it?**
Moducare™ is considered a daily supplement and should be taken as long as it is required for it to aid
the immune system to be balanced. Sterols and sterolins do not "fix" the immune system but give it
the nutrients it needs to be balanced. However, it is suggested that periodic breaks be taken as to
avoid the body's natural immune system from becoming lazy. Exact protocols should be discuss with
either a medical professional or pharmacist.

**How should Moducare™ be given?**
Cats: the recommended dosage is one capsule per day, preferably split half in the morning and half in
the evening. It can be safely fed with meals as the dosage is high enough to remain effective. In the
case of cats with FIP or any other immune issues a loading dose of 2 capsules a day can be given
(kittens are dosed at half the adult dose).

**Must Moducare™ be taken on an empty stomach?**
Moducare™ is advised to be taken on an empty stomach for humans - one half hour before or two
hours after a meal for maximum absorption. However, it can be taken with fruits and vegetables, nuts
and seeds.
The important thing is to take it AWAY from cholesterol (animal fat), including all meat, dairy, eggs,
seafood, etc. Cholesterol has a very similar molecular structure and the two compounds "compete" for
absorption. You can also take Moducare™ with beverages, as long as they contain no cholesterol.

The recommendation for cats is that due to the dosage being high it can safely be sprinkled over food,
or given with a pill popper, and still remain effective.

**Can you take too much?**
No. It is impossible to overdose on Moducare™. The body has a limited capacity to absorb these plant
fats, and any excess is excreted harmlessly in the intestine.

**What if there is an allergy to pine? Since Moducare™ is extracted from pine, is there anything in the
supplement that would cause a similar allergic reaction?**
Moducare™ contains only the isolated molecules of the sterols and sterolins which have been
extracted from pine trees (Pinus Maritima and Pinus Pinaster). There is none of the original plant in
the final product. If you looked at these plant fat molecules in a laboratory, you would not be able to
tell if they had been extracted from oranges, peas, almonds, etc.

**Is Moducare™ the same as Pine Bark extract?**
No. Pine bark is an antioxidant and works differently in the body from the plant fats. Both are

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phytonutrients, meaning they are derived from plants.

*How long before results can be seen?*
As with many natural supplements, it can take a period of time before an improvement is noticed.

**Veterinary applications for Moducare™**

Yes, many veterinarians use the product in their practice.

**Suggested amounts for cats and dogs:**
One capsule per day for cats and small dogs
One capsule twice per day for dogs over 50 pounds / 22 kgs

Half the dose for kittens and puppies
For FIP Cats (who are not taking Polyprenyl Immunostimulant) a loading dose of 2 capsules per day should be given.

**Peer reviewed studies of Professor Bouic’s research.**
This is an article appearing in the South African Journal of Natural Medicine, Volume 1, 2000, pg 23 - 25. While the study was directed on humans it can be extrapolated to include those animals such as cats, dogs, horses etc. as well due to the the fact that the processes involved in the way Moducare™ works are the same across the board. Part of the study did involve cats with FIV and this paragraph has been highlighted in bold and italicized.

**MODUCARE™ AND THE IMMUNE SYSTEM**
By Prof. P J D Bouic (BSc, AEA Immunology, AEA Pathology, DERBH Immunology, Ph.D. Immunology, Head of Immunology, University of Stellenbosch / Tygerberg Hospital)

Sterols and sterolins are essential nutrients not produced by the body. They can only be obtained through natural sources. Shown to have anti-inflammatory, anti-allergic and anti-cancer properties. They join the ranks of other essential nutrients like amino acids, essential fatty acids and Vitamin C.

Beta-sitosterol (BSS) is the major phytosterol in higher plants and is found in the serum and tissue of healthy individuals at concentrations 800 - 1000 times lower than that of endogenous cholesterol. Its glycoside, beta-sitosterol glycoside (BSSG), is also present in serum, but at even lower concentrations (1). Only plants can synthesize these molecules, while animals, including man, obtain them through their diets. Many epidemiological studies conducted in population groups consuming diets rich in vegetables and fruits have indicated a reduced incidence of various types of cancer, cardiovascular diseases, diabetes and other chronic diseases. (2)

It has been shown that BSS can reduce carcinogen-induced cancer of the colon in rats; (3) it also shows anti-inflammatory, (4) antipyretic (5) and anticomplement activity, (6) as well as insulin-

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releasing effects. (7) Similar effects have been described for the glucoside of BSS. Many plant extracts described for their medicinal properties have BSSG as an obligatory component.

We have studied the effects of a BSS and BSSG mixture (Moducare™) on the functioning of human immune cells, and have found this mixture to have profound immune-modulatory activities. From simple in vitro observations, we have moved on to clinical trials in patients with chronic infectious diseases (tuberculosis, HIV, human papillomavirus [HIV]) and even non-infectious conditions such as allergies and rheumatoid arthritis. To date, the importance of this natural plant mixture in the management of such conditions.

**Sterols/sterolins as adjuvant therapy in the treatment of patients with pulmonary tuberculosis.**

The first clinical study conducted using Moducare™ looked at its adjuvant activity in culture-proven pulmonary tuberculosis. All patients were treated with the standard anti-tuberculosis regime. Both groups became sputum negative at the same time. There was a significant difference in the blood picture between the two groups with a remarkable weight gain over the 6 month period in the Moducare™ treated group. This was the first study to indicate that the intake of the plant sterol/sterolin mixture had a beneficial outcome in pulmonary tuberculosis.

**Sterol/sterolin mixture in the feline immunodeficiency virus (FIV)-positive cat:**

*a model of HIV* We were able to obtain domestic cats infected with the FIV retrovirus, considered the equivalent to HIV in that it induces the same pathogenic mechanism of CD4 cell loss and opportunistic infections. The infected cats finally succumbed to the immuno-suppressive state. We therefore considered this an ideal opportunity to study the immune-modulatory activity of Moducare™ before it is investigated in humans. A group of 33 infected cats was divided into a treatment group (16 cats) and a placebo group receiving capsules containing the pharmaceutical carrier only. There were 17 cats in this group. (8) Moducare™ and the Immune System (1)

The treated group maintained stable immune cells over a period of 168 weeks, whereas those that received the placebo capsules showed disease progression and the typical CD 4 cell loss over the same period. At present, cats treated with the BSS/BSSG mixture show only 22% mortality compared with 86% in the non-treated group.

**Moducare™ and its use in preventing stress-induced immune suppression**

Excessive exercise is known to induce profound changes in physiological parameters, of which immune competence is possibly the best studied. This is because individuals participating in marathon running or other related endurance events are prone to respiratory, bacterial and viral infections. Research has shown that this susceptibility is due to transient hormone-induced redistribution in immune cells, as well as a decline in the functionality of the cells. (9) We undertook to investigate the potential of BSS/BSSG in inhibiting (albeit partially) certain parameters indicative of immune suppression in a group of volunteers participating in an ultra-marathon event. This was a double-blind, placebo-controlled study.

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The study indicated that the hematological changes that accompany endurance exercise were more pronounced in individuals who received placebo capsules than in those who received the active capsules.

Possibly the most dramatic differences between the groups in the study were both the decline in inflammatory immune cells and a decline in the levels of cortisol with a parallel increase in serum DHEA levels (immune regulatory hormones) in the volunteers who ingested the BSG/BSSG capsules. The modulation of such hormones has a direct impact on the redistribution of lymphocytes during stress episodes and significantly affects the immune challenge.

**Ongoing clinical studies with the plant sterol/sterolin mixture**

At present, new clinical studies are being conducted with regard to the following conditions:

- Rheumatoid arthritis
- Cervical lesions induced by human papillomavirus
- Chronic rhinitis and sinusitis
- Hepatitis C virus carrier status

**Dosages and recommendations**

Many questions arise as to why one would need to supplement one's diet with such plant molecules, even in the face of apparently normal immune functions. Being natural and present in all vegetables and fruits, one would expect to obtain sufficient quantities of the phytosterols via the natural route. The answer to this lies in the fact that the plant sources richest in sterols and sterolins are refined to prevent the precipitation of these fats in the foods.

A good example of this is the cold-pressed virgin oils, known for their turbidity and ‘milky’ appearances. This precipitate is, in fact, the fats that have not been hydrolyzed and removed from the oils. It suffices to compare refined oils with virgin oils to understand and appreciate the impact of the food industry's refinement procedure on the lack of intake of sterols/sterolins and other important phyttonutrients in our diets. Another reason why the intake of these molecules is limited lies in the fact that we have become more carnivorous over the last 5 to 6 decades - our intake of vegetables and fruits has decreased at the expense of intake of meats. It is difficult to determine any overt deficiencies of plant phytosterols in any individual.

**We believe that due to the incorrect dietary habits of most people, the intake of these important phyttonutrients is limited and possibly explains our ‘stressed’ existence, leading to the development of many chronic diseases of modern society.**

There are no RDA recommendations concerning the intake of plant sterols/sterolins. On the other hand, due to the metabolic control of their uptake, it is impossible for anyone to overdose on these molecules; the pharmacological pools of the plant phytosterols are strictly controlled, and any excess

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is excreted via the stools. However, any diet devoid of phytosterols leads to a rapid decline in such pools. (10)

For someone who wants to use the sterols/sterolins as a management strategy for any chronic disease or immune disorder, the recommended dose is to have a loading phase of double dosages, namely 6 capsules per day for 7 days, and then a maintenance dosage of 3 per day. It is recommended that the capsules should be taken on an empty stomach at least an hour before meals. This prevents any eventual competition between the plant fats and dietary-derived cholesterol. Most patients report benefit after 10 - 14 days of the intake of the Moducare™ capsules, depending on the grade/severity of the symptoms. When pain is involved, it starts disappearing after a week, and this is easily monitored by the patient. When it involves other diseases such as chronic viral infection, only laboratory markers (e.g. CD 4 cell count, viral loads, etc.) can be used to monitor clinical efficacy.

**Conclusions**

Moducare™ is a new, natural immune modulator composed of a mixture of BSS and BSSG, more commonly known as sterols and sterolins. This mixture has shown promising results under clinical trial conditions. There are several new clinical studies being undertaken at pre-data to prove Moducare™’s important role in the management of patients with chronic immune-mediated processes or abnormalities.

Further evidence of the validity of Moducare™ as a scientifically proven supplement is an article extracted from the National Center for Biotechnology Information which forms part of the National Institutes of Health (NIH), one of the world’s foremost medical research centers and an agency of the U.S. Department of Health


**Abstract**

Beta-sitosterol (BSS) and its glycoside (BSSG) are sterol molecules which are synthesized by plants. When humans eat plant foods phytosterols are ingested and are found in the serum and tissues of healthy individuals, but at concentrations orders of magnitude lower than endogenous cholesterol.

Epidemiological studies have correlated a reduced risk of numerous diseases with a diet high in fruits and vegetables, and have concluded that specific molecules, including b-carotene, tocopherols, vitamin C, and flavonoids, confer some of this protective benefit. However, these epidemiologic studies have not examined the potential effect that phytosterols ingested with fruits and vegetables might have on disease risk reduction. In animals, BSS and BSSG have been shown to exhibit anti-inflamatory, antineoplastic, antipyretic, and immune-modulating activity.

A proprietary BSS:BSSG mixture has demonstrated promising results in a number of studies, including in vitro studies, animal models, and human clinical trials. This phytosterol complex seems to target specific T-helper lymphocytes, the Th1 and Th2 cells, helping normalize their functioning and resulting in improved T-lymphocyte and natural killer cell activity. A dampening effect on overactive

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antibody responses has also been seen, as well as normalization of the DHEA:cortisol ratio.

The re-establishment of these immune parameters may be of help in numerous disease processes relating to chronic immune-mediated abnormalities, including chronic viral infections, tuberculosis, rheumatoid arthritis, allergies, cancer, and auto-immune diseases.

So what are some of the applications of Moducare™?

**Allergies – allergic rhinitis/hay fever**
Allergies are caused by an overactive immune system. They are reacting to various “triggers” in their environment that produce an allergic response, e.g. pollen, grass, cat hair, perfume. The ideal way of dealing with allergies is at the cellular level before specialized immune cells (mast cells) start releasing histamine.

Plant sterols and sterolins have been shown in research to decrease the overactivity of the immune system. They decrease the specific immune factor (Interleukin 4) that ultimately causes the allergic response and the release of histamine. Therefore, it is beneficial for allergy sufferers to try to balance their immune system with sterols and sterolins.

**Autoimmune Diseases**
Plant sterols and sterolins “modulate” or balance the immune system and have been shown to decrease the auto-antibody production.

**Weakened Immune System and Immune Related Diseases**
Plant sterols are an effective immune balancer. Sterols and related compounds called sterolins are special fats found in plant foods, such as seeds, nuts, and plant oils. Sterols and sterolins have been shown to restore immune balance, which is beneficial for those with infections, stress-induced immune suppression, allergies, or rheumatoid arthritis and other autoimmune conditions [Alternative Medicine Review, 2001, vol. 6, no. 2] The use of the mixture by HIV-infected individuals has been extensively studied. It has been shown to prevent the decline of CD4 cell numbers (a surrogate marker of disease progression), decrease the plasma viral loads of patients and maintain a relatively intact immune profile despite the chronic viral infection. This implies that the use of the immune modulator (such as Moducare™) by HIV-infected individuals would prevent the deterioration of the immunity and the maintenance of effective cellular responses to the virus. [S.Afr. Med. J. (2001) 91, pp.848-850, Cell Biol. Int. (2001) 25, pp.43-49]

**Infections**
Various studies showed that patients having received Moducare™ had less inflammation and less frequent outbreaks of various infectious diseases such as Tuberculosis, Sinusitis, Herpes I and STD Herpes II

**Lab Values**

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Stress can have a significant impact on the body, particularly the immune system. With chronic stress, the adrenal glands secrete excess cortisol. This overproduction of cortisol can lead to the death of cells in our immune system, e.g. lymph nodes, spleen, thymus gland.

The link between stress and autoimmune disorders lies with the balance between cortisol and DHEA. An increase in stress leads to an increase in cortisol and a decrease in DHEA. High levels of cortisol cause immune cells to make more factors that lead to the production of autoantibodies. A balance between cortisol and DHEA is essential for optimum immune function.

Research has shown that sterols and sterolins lower cortisol levels in the body and normalize DHEA thus achieving a balance between these two hormones.

The mechanism of the cholesterol-lowering activity of phytosterols is not fully understood. Phytosterols appear to inhibit the absorption of dietary cholesterol and the reabsorption (via the enterohepatic circulation) of endogenous cholesterol from the gastrointestinal tract. Consequently, the excretion of cholesterol in the feces leads to decreased serum levels of this sterol. Phytosterols do not appear to affect the absorption of bile acids. It is believed that phytosterols displace cholesterol from bile salt micelles. Another proposed mechanism is the possible inhibition of the rate of cholesterol esterification in the intestinal mucosa.

In addition to all the above Moducare™ has also been shown to have a positive effect on the musculoskeletal health of patients in terms of aiding Rheumatoid Arthritis as well as Hepatic issues relating to organ health.

**Where to buy:**

Moducare™ is an OTC supplement that can be purchased online and at various health stores worldwide. There are several companies selling Moducare™, however our preference goes to two brands, Thorne and Aspen. Aspen Pharmaceutical was the original manufacturer of Moducare™ and have maintained the original formulation of a 1:100 ratio of Plant Sterolins 0.2mg and Plant Sterols 20mg derived from Maritime Pine. Both Aspen and Thorne retain this ratio and have the same carrier (inactive ingredients) Any generic product will usually have the same active ingredients but use an alternative carrier, and as such it is important to assess the inactive ingredients for safety in use in cats.

Some Moducare products are paired with other supplements such as Vitamin D3, Echinacea and such. Always remember that these formulations are for human treatment and animal owner must be aware of toxicity issues that any of the further additives may hold. In and of itself Vit D3 is beneficial but too a high a dose can be fatal. A number of these formulations, although still keep the 1:100 ratio of sterols to sterolins, mix it at a ratio of 0.6mg to 60mg. If that is the case then remember that you need to reduce the quantities given – only a third of the capsule must be given. The use of only the original Moducare formulation is therefore suggested and recommended.

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Thorne Pharmaceuticals are to date the only company with a dedicated veterinary use product for Moducare.

Online Suppliers:

Buy on Amazon.com (Thorne's Moducare™ can also be purchased on Amazon's other countries websites).

Buy Aspen's Moducare™ on Iheal.co.za in South Africa (worldwide shipping available)

Buy on iHerb

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