

## ALLERGEN-FREE/VEGETARIAN FORMULAS

### PRODUCT INFORMATION

**Product Name:**

Moducare

**NPN:**

Capsule: 80003342

Tablet: 80007670

**Galenic Form:**

Vegetable Capsule

Chewable Tablet

**Format:**

Moducare® capsules in bottles of 90 or 180 capsules.

Moducare® Grape Chewables in bottles of 60 tablets.

**Ingredients:**

Each capsule/chewable tablet contains:

Beta-sitosterol (from pine tall oil pitch)..... 20 mg

Beta-sitosterolin ..... 0.2 mg

**Non-medicinal ingredients:****Capsules:**

Rice flour, magnesium stearate, silicon dioxide, cellulose, hypromellose.

This product does not contain corn, dairy, egg, gluten, shellfish, soy, sulfites, animal derivatives or artificial colours, flavours or preservatives.

**Tablets:**

Cellulose, xylitol, natural grape flavour, citric acid, malic acid, inulin, silicon dioxide, magnesium stearate.

This product does not contain dairy, egg, gluten, shellfish, soy, sulfites, animal derivatives or artificial colours, flavours or preservatives.

**Formula Rationale:**

*RxBalance™ Moducare®* is a proprietary mix of plant sterols and sterolins derived from a natural pine source in a clinically proven ratio of 100:1.

Moducare® is the only clinically tested plant sterol/sterolin product proven to be effective in immune modulation.

Research has shown that Moducare® targets specifically CD4 cells of the TH1 phenotype.

There is a partial explanation for this: genes coding for IL12 (the cytokine that directly targets TH1 cells) are up-regulated in preference to genes that code for other cytokines.

Moducare® is a safe, effective immune modulator and has been shown, both in vitro as well as in vivo, to have the following immunological activities:

- Enhances the cellular division of peripheral blood lymphocytes when these are activated by stimuli;
- Enhances the killing ability/cytotoxicity of specialized cells responsible for immune surveillance, namely the Natural Killer cells (NK cells);

- Enhances the ability of T lymphocytes to release the factors that ultimately regulate cellular functions in the body. These T cells (TH1 helper cells) are antagonist to the activity of other helper cells (TH2) that promote the functions of B lymphocytes;
- The mixture of sterols/sterolins has anti-inflammatory properties by switching off the release of proinflammatory factors such as Interleukin 6 (IL6) and Tumor Necrosis Factor-alpha (TNF- $\alpha$ ) from activated monocytes;
- Increases the secretion of IL12, the cytokine released from antigen-presenting cells that promotes the differentiation of precursor T-helper cells into the more polarized TH1 cells;
- The mixture has adreno-cortical effects by decreasing the cortisol: DHEA ratio suggestive that it enhances the synthesis of DHEA, which ultimately, decreases the release of cortisol.

**Primary indication(s):**

Helps support a healthy immune system balance.

**Recommended dosage:**

*Adults and children 17 years and over:* Take 1 capsule/tablet three times daily OR 2 capsules/tablets upon arising and 1 capsule/tablet before bed.

*Children 11 to 16 years:* Take 1 capsule/tablet, twice daily.

*Children 5 to 10 years:* Take 1 capsule/tablet, one to two times daily.

For best results, take with water or juice between meals on an empty stomach. Use for a minimum of two to three months to see a beneficial effect.

**Complements:**

Kyolic (immune support), Aller-Plex (seasonal allergies).

**Caution:**

Not to be used by organ and tissue transplant recipients, including bone marrow and corneal transplants, individuals with a history of Type I diabetes or multiple sclerosis, unless on the advice of and under the direct supervision of a health care practitioner. Do not use if you are pregnant, breastfeeding or have sitosterolemia. Some individuals may experience temporary digestive problems, rashes, headache and fatigue.



**Dr. Crisafi's comments:**

After almost 30 years of clinical practice and about 25 years as a writer/commentator in the natural product industry, I have heard more than my share about "miraculous" natural products. Fortunately, though many come, almost as many go. Few products have had the staying power of Moducare®.

In my practice I have had the chance to recommend Moducare® to patients in a wide variety of situations with excellent - sometimes surprising - results.

Allergies (environmental as well as food) and food intolerances are on the increase. Though we may suggest several causes for this increase, certain factors seem quite consistent. The first, and most important, is a weakening of immune function. Indeed, if we assess an allergy correctly, we will notice that the immune system overreacts to a potential aggressor. Some of the reactions - anaphylaxis, urticaria etc - that take place when an individual is confronted with a substance are disproportionate reactions. Peanuts are not that dangerous, and the immune system should not react as excessively as it does when someone consumes them. The immune system generally overreacts when it is too weak.

The overuse of antibiotics, not giving the immune system the chance to fend for itself, and excessive asepsis, not supplying enough challenges for the immune system to develop normally, are the two major challenges to immune function.

Moducare modulates immune function by improving normal immune response, reducing disproportionate or excessive responses and increasing weakened immune response. Simply put, if the immune system is strong enough it does not have to over-react to a challenge.

In our clinic Moducare® has been used successfully (and rapidly) for children or adults who have environmental sensitivities, food allergies or intolerances and seasonal allergies.

While working on their lifestyle challenges patients with recurring infections, including otitis, bronchitis, sinusitis and the flu have responded very well with Moducare®. A surprisingly rapid effect can often be seen in individuals with seasonal allergies.

We have especially found Moducare® useful with children who have a variety of immune reactions.

Stress invariably reduces immune competence. Moducare's sterinols have been shown to improve the negative impact on stress by normalising cortisol/DHEA ratios.

**Selected References**

- Bouic PJD, et al. *Plant sterol/sterolin supplement use in a cohort of South African HIV infected patients - effects on immunological and virological surrogate markers.* South African Med J (2001); 91:848-50.
- Bouic PJD. *Sterols and sterolins: new drugs for the immune system?* Drug Discovery Today 2002; 7:775-78.
- Bouic, PJD and Lamprecht, JH: *Plant sterols and sterolins: a review of their immune-modulating properties.* Alt Med Rev 1999; 4:170-177.
- Bouic, PJD: *The role of phytosterols and phytosterolins in immune modulation: a review of the past 10 years.* Curr Opin Clin Nutr Metab Care 2001; 4,471-475.
- Breytenbach, U. et al: *Flow cytometric analysis of the Th1-Th2 balance in healthy individuals and patients infected with the human immunodeficiency virus (HIV) receiving a plant sterol/sterolin mixture.* Cell Biol Int 2001; 25, 43-49.
- Louw, I., et al. *A pilot study of the clinical effects of a mixture of Betasitosterol and Beta-sitosterol glucoside in active Rheumatoid Arthritis (RA).* Am. J. Clin. Nutr. (2002) 75, Abstract 40, 351S.
- Bouic PJD, Clark A, Lamprecht J, Freestone M, et al. *The effects of β-sitosterol (BSS) and β-sitosterol glucoside (BSSG) mixture on selected immune parameters of marathon runners: inhibition of post marathon immune suppression and inflammation.* Int J Sports Med 1999; 20:258-62..
- Pegel, KH: *The importance of sitosterol and sitosterolin in human and animal nutrition.* S A J Sci 1997; 93: 263-268

