

ALLERGEN-FREE/VEGETARIAN FORMULAS

PRODUCT MONOGRAPH

Immune System Balancer

RxBalance™ Moducare® helps support a healthy immune system balance. Moducare® is a proprietary mix of plant sterols and sterolins, in a clinically proven ratio of 100:1. RxBalance™ Moducare® Chewable is a grape-flavoured chewable tablet version of Moducare®. This alternative delivery system was developed for children and for adults who have difficulty swallowing capsules. Each tablet contains the exact formulation of sterols and sterolins as in the original Moducare® capsule.

Ingredients: Medicinal

Each capsule/tablet contains:

Beta-sitosterol (from pine tall oil pitch)	20 mg
Beta-sitosterolin	0.2 mg

Ingredients: Non-medicinal

Capsule:

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.

Tablet:

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

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

Recommended Use

Helps support a healthy immune system balance.

Recommended Dose

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.

Risk Information

Not to be used by organ and tissue transplant recipients, including bone marrow and corneal transplants, or individuals with a history of 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.

Interactions with Drugs/Supplements

There are no known interactions, to date, with Moducare® and any prescribed medications or natural supplements.

Dosage Form Description

Moducare® capsules contain a beige-white powder fill. Moducare® Chewables are marketed as a 5/8" round light pink chewable tablet with dark pink speckles and a grape taste.

Packaging

Moducare® capsules are available in bottles of 90 or 180 capsules. Moducare® Grape Chewables are available in bottles of 60 tablets.

Stability

3 years when stored in a cool dry location.

Ingredient Description

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® specifically targets 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.



Reasons for Use

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 stimuli¹;
- Enhances the killing ability/cytotoxicity of specialized cells responsible for immune surveillance, namely the Natural Killer cells (NK cells)¹;
- 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 antagonists to the activity of other helper cells (TH2) that promote the functions of B lymphocytes²;
- 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- α) from activated monocytes³;
- 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, suggesting that it enhances the synthesis of DHEA, which ultimately decreases the release of cortisol⁴.

Research Synopsis

1. A double blind, placebo-controlled 6 month pilot study of the clinical effects of a mixture of Beta-sitosterol and Beta-sitosterol glucoside in active Rheumatoid Arthritis with 18 subjects. Conclusions: Based on mean tender joint count, patient's assessment of pain, patient's global assessment of disease activity, physician's global assessment of pain and MHAQ, there were statistically significant changes noted in active group⁵.
2. Plant sterol/sterolin supplement use in a cohort of South African HIV infected patients - an open label, 39 month study of 123 subjects to evaluate Moducare®'s effects on immunological and virological surrogate markers. HIV positive patients (CD4 > 500/ul) had a significant reduction in plasma viral load at 30 months (undetectable for 15% of patients at 12 months), but exhibited no changes in the CD4 immune markers. HIV positive patients with CD4 < 200/ul and those with CD4 between 200 to 500/ul showed no significant change in plasma viral load⁶.

3. The effects of β sitosterol (β SS) and β -Sitosterol Glucoside (β SSG) Mixture on Selected Immune Parameters of Marathon Runners: Inhibition of Post Marathon Immune Suppression and Inflammation, a double blind, placebo-controlled 31 day study. Runners using Moducare had significantly decreased Cortisol to DHEA ratios. Interleukin 6 significantly decreased in runners using active capsules. Lymphocyte subsets CD3+, CD4+ cells significantly increased in runners using active capsules. White blood cell and neutrophils significantly increased numbers in placebo group. There was significantly less neutrophilia, lymphopenia and leukocytosis in runners using the active capsules⁷.

References

1. Bouic PJD et al (1996): *Int. J. Immunopharmacol.* 18, 693-700.
2. Bouic PJD & Lamprecht JH (1999): *Alt. Med. Rev.* 4, 170-177.
3. Bouic PJD (2001): *Curr. Opin. Clin. Nutr. Metab. Care* 4, 471-475.
4. Bouic PJD (2002): *Drug Disc. Today* 7, 775-778.
5. Louw, I., et al. A pilot study of the clinical effects of a mixture of Beta-sitosterol and Beta-sitosterol glucoside in active Rheumatoid Arthritis (RA). *Am. J. Clin. Nutr.* (2002) 75, Abstract 40, 351S.
6. 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.
7. Bouic PJD, et al. "The effects of β sitosterol (β SS) and β -Sitosterol Glucoside (β SSG) Mixture on Selected Immune Parameters of Marathon Runners: Inhibition of Post Marathon Immune Suppression and Inflammation." *Int J Sports Med.* (1999); 20: 258-262.

PRODUCT CODES: 403 100 - 90 Vegetable Capsules
403 110 - 180 Vegetable Capsules
403 120 - 60 Grape Chewable Tablets

RX BALANCE

6 Commerce Crescent, Acton, ON L7J 2X3
1-877-929-2548

