

Consumer leaflet

Please read this leaflet carefully because it provides important information. Immulina is a dietary supplement, sold in pharmacies and health food shops without prescription. According to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 the labelling of a dietary supplement must not attribute to it the property of preventing, treating or curing a human disease, or refer to such properties.

Immulina[®]

Dietary supplement
Boosts innate immune system

Composition given for 1 capsule, the minimum daily dose:

Standardized *Arthrospira platensis* extract - 100 mg* corresponding to approx. 0.75 g of spirulina

Composition given for 4 capsules, the recommended daily dose:

Standardized *Arthrospira platensis* extract - 400 mg* corresponding to approx. 3.0 g of spirulina

* RDA (recommended daily allowance) has not been established.

Accessory substances: dicalcium phosphate E 341 (stabilizer), cellulose microcrystalline E 460 (carrier), magnesium stearate E 470b (carrier), gelatin E 441 (capsule shell), titanium dioxide E 171 (color).

Properties and mode of action:

Immulina provides LCEPEEN[™] - special extract that shows effect enhancing immune system more effectively than any other available preparation.

Spirulina is a concentrated and lyophilized commercial product of microalgae *Arthrospira platensis*^[1]. Spirulina Extract provides the bioactive lipopolysaccharide complex, so called LCEPEEN, obtained in a special, patented extraction process^[2,3]. This complex, when taken orally, does not absorb from GI tract and it is phagocytized by macrophages and dendritic cells, so called antigen-presenting* cells, causing their stimulation. The stimulated cells migrate to the Peyer's patches - lymphoid tissue of GI (so called GALT[†]) and stimulate the whole immune system. Lipopolysaccharide (LPS) complex obtained from cell wall of bacteria *Escherichia coli*, called endotoxin, is the most powerful immunostimulant traditionally used in laboratories. However, the LPS complex (LECPEEN^[4]) in ImmuMax is 10 times more potent than endotoxin in the activation of macrophages. This is due to the fact that LECPEEN acts through TLR2 receptors while endotoxin acts through TLR4 receptors. The density of TLR2 receptors on dendritic cells is much higher (2.5 times) than that of TLR4 receptors. This may explain the higher potency of LECPEEN.

The preclinical data obtained with LECPEEN indicate that it stimulates cells of the innate and adaptive immune system. It directly activates cells of the monocyte-macrophage lineage in part via TLR2 and CD14 receptors^[5]. In cell culture, THP-1 cells respond to LECPEEN

* Antigen-Presenting Cells - (APCs) are cells that display foreign antigen complexes with *major histocompatibility complex* (MHC - determines compatibility of donors for organ transplant) on their surfaces. APCs are very efficient at internalizing antigen, either by phagocytosis or by receptor-mediated endocytosis, and then displaying a fragment of the antigen, bound to a class II MHC molecule, on their membrane to the other elements of the immune system. There are three main types of antigen-presenting cell: dendritic, macrophages and B lymphocytes.

† GALT - the digestive tract's immune system is often referred to as gut-associated lymphoid tissue and works to protect the body from invasion. The digestive tract is an important component of the body's immune system. In fact, the intestine possesses the largest mass of lymphoid tissue in the human body. The GALT is made up of several types of lymphoid tissue that store immune cells, such as T and B lymphocytes, that carry out attacks and defend against pathogens. Peyer's patches are organized lymphoid nodules and belong to GALT.

directly with an increased production of cytokines and chemokines. In their activated state, macrophages can destroy bacteria and virus-infected cells. In this state, macrophages also stimulate NK cells through an increased production of cytokines (TNF- α , IL-12 and IL-18). It is by this mechanism that LECPEEN can enhance the activity of NK cells^[6] that are key players in the host defence against tumour cells.

Immulina[®] is dietary supplement designed to enhance innate immune system[‡]. Preparation may be taken by anybody, however it is particularly recommended for people with impaired function of immune system. The weak immune system may manifest in recurrent and/or prolonged infections and allergy. Regular usage of Immulina supports restitution (return) of immune system during and after treatment with antibiotics, x-ray-, chemotherapy and in case of physical exhaustion. It also reduces cold sore recurrence, improves skin condition (in acne particularly), reduces skin ageing and reduces muscle pain after intensive physical exercise if taken in beforehand. It is also helpful in alleviating joint problems.

Recommended usage (administration): One or two capsules once a day after a meal with glass of water. In case of an early infection and/or impaired immune function the dose can be doubled. One should not exceed the recommended daily dose.

Available packages: 30 capsules; 2 blisters containing 15 capsules, 60 capsules 4 blisters containing 15 capsules, and Immulina forte 30 capsules providing 200 mg of LCEPEEN.

Additional remarks: not recommended for pregnant or breast feeding women. The product should be stored out of the reach of young children and at room temperature. Dietary supplement cannot be used as a substitute for a varied diet. The expiry date is on the box close to the bar code.

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ImmuMax[™] is registered trade mark of Phytomedica Polska Company.

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References:

¹ Chamorro G, Salazar M, et al. *Pharmacology and toxicology of Spirulina alga*; Rev Invest Clin (1996) 48:389-399,

² Pugh N, Pasco D.S.; *Immulina Polysaccharide a Potent Activator of Monocytes*; 2001, Univ. Mississippi Protoc.

³ Krishnakumari MK, Ramesh HP, et al. *Food safety evaluation: Acute oral and dermal effects of the algae, Scenedesmus acutus and Spirulina platensis, on albino rats*; J Food Prot 44:934-935.

⁴ Pugh N, Ross S.A, et al. *Isolation of Three High MolecularWeight Polysaccharide Preparations with Potent Immunostimulatory Activity from Spirulina platensis, Aphanizomenon flos-aquae and Chlorella pyrenoidosa*; Planta Med 67 (2001) 737-742,

⁵ Balachandran P, Pugh N. et al. *Toll-like receptor 2-dependent activation of monocytes by Spirulina polysaccharide and its immune enhancing action in mice*; Int. Immunopharm. 6 (2006) 1808-1814,

⁶ Lydeking-Olsen E, Lydeking-Olsen H, et al. *Immulina in autoimmune diseases*; Institute for Optimum Nutrition, Denmark, RMG Biosciences, Inc., United States,

[‡] Animal studies have shown that LCEPEEN activates antigen presenting cells, forming a link between native cells of immune system and lymphocytes B and C of the adaptive immune system. Spirulina extract enhances IgA and IL-6 production by cells isolated from Payer's patches and interferon- γ by spleen cells. It has been shown that this extract is 10 times more potent than *spirulina* from which it is originated.