

Consumer leaflet

Please read this leaflet carefully because it provides important information. ImmuMax syrup 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".

ImmuMax®

Dietary Supplement

Syrup for Children

Boosts the Immune System

Composition given for 2.5 ml, the minimum daily dose:

Standardized *Arthrospira platensis* extract 50 mg* corresponding to approx. 0.375 g of spirulina, β -1,3/1,6-D glucan 37.5 mg*, Acerola fruit extract (*Malpighia glabra*) 40 mg* providing 10 mg C vitamin = 12.5 % RDA.

Composition given for 10 ml, the maximum daily dose:

Standardized *Arthrospira platensis* extract 200 mg* corresponding to approx. 1.5 g of spirulina, β -1,3/1,6-D glucan 150 mg, Acerola fruit extract (*Malpighia glabra*) 160 mg providing 40 mg C vitamin = 50 % RDA.

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

Accessory (inactive) ingredients: Purified water, cherry flavour, sugar, potassium sorbate (E202) natural food preservative, acacia gum (E414) natural stabilizer.

Recommended usage: Shake the bottle thoroughly before each use. To be taken during meals. The children older than 1 year: ½ measure (2.5 ml), children older than 3 years: 1 measure (5 ml) once a day. In case of an early infection and/or depressed immune function the dose can be doubled. Do not exceed the recommended daily dose.

Properties and mode of action: ImmuMax syrup provides three active ingredients: spirulina extract, acerola extract and β -glucan with proven and a documented positive effect on immune system. These actives show synergistic effect* enhancing immune system more effectively.

Spirulina extract: it is a concentrated and lyophilized commercial product of microalgae *Arthrospira platensis*. It provides the bioactive lipopolysaccharide complex, so called LECPEEN, obtained in a special, patented extraction process. 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 lymphoid tissue of GI (so called GALT[‡]) and stimulate the whole immune system. Lipopolysaccharide 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) 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. In cell culture, THP-1 cells respond to LECPEEN 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 that are key players in the host defense against tumor cells.

β -1,3/1,6-D-glucan is derived from the cell wall of baker's yeast (*Saccharomyces cerevisiae*). The most active forms of β -glucans are those comprising D-glucose units with (1,3) links and with side-chains of D-glucose attached at the (1,6) position. These are referred to as β -1,3/1,6 glucan. β -glucans are known as "biological response modifiers" because of their ability to activate the immune system. After it is taken orally, it does not absorb from GI tract and it is phagocytized by macrophages and dendritic cells, so called antigen-presenting cells, causing their stimulation and through them the whole immune system. In several studies it has been shown that β -glucan activates macrophages, NK cells, and increases ability to produce cytokines and complement. Immunologists at the University of Louisville discovered that Complement Receptor 3 (CR3) is responsible for binding to β -glucans, allowing the immune cells to recognize them as "non-self". Several clinical studies have shown that β -glucan administration significantly reduces risk of infection

and infectious complications.

Acerola fruit extract (*Malpighia glabra vel emarginata*), so called Barbados cherry, is known for being extremely rich in vitamin C, the highest vitamin C content measured in any fruit. One acerola fruit weighing approx. 4.5 g has as much C vitamin as one kg of lemon fruits. One small glass (180 ml) of acerola juice may contain as much C vitamin as 3.5 gallons of orange juice. It also contains substantial amount of vitamins A, B1, B2 and B3 as well as carotenoids, bioflavonoids and minerals (calcium, phosphorous, iron), which provide very important nutritive value and have antioxidant uses.

The C vitamin in acerola fruit is provided in a bioflavonoid complex (together with **rutin** and **hesperidin**), which is better absorbed by human organisms than synthetic ascorbic acid. Vitamin C in this complex is also more stable and continuously released that enhances its activity. Moreover, rutin and hesperidin have beneficial influence on immune system and blood vessels. Vitamin C plays many functions in the body i. a. enhances immune system, increases resistance to infection, counteract tiredness and fatigue.

ImmuMax syrup is a dietary supplement that strengthens our immune system. ImmuMax consumption is particularly beneficial for children with a weakened immune system. An impaired immune system may manifest itself in many ways e.g. proneness to infections or recurrent infections and allergy. Regular usage of ImmuMax syrup supports immune system during or after treatment with antibiotics, x-ray-, chemotherapy and in cases of physical exhaustion. It also reduces cold sore recurrence, improves skin condition (in acne), and reduces muscle pain after intensive physical exercise if taken beforehand. It is also helpful in alleviating joint problems.

Additional remarks: Do not use if you are allergic to any ingredient. Do not use after expiry date. Consult your health care professional before administering to children below the age of 1 or to pregnant or nursing women. A dietary supplement cannot be used as a substitute for a varied diet.

The product should be stored out of the sight and reach of young children at room temperature and after opening in the fridge. This syrup is a natural product and therefore the taste may vary, and the bottle may contain precipitation, which does not constitute any product fault.

Available packages: bottle containing 250 ml of syrup.

Manufactured in EU. Marketing authorisation: Phytomedica Co. Ltd. Phone: + 48 22 550 60 30, info@phytomedica.pl, www.phytomedica.pl. ImmuMax™ is registered trade mark of Phytomedica Co. Ltd.

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*Synergy - joint action of two or more agents (drugs) that, taken together, produce a greater effect than the sum of their individual effects.

[†]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 - 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.