



LACTOBACILLUS DELBRUECKII LE™

Introducing: Vivoflora's *Lactobacillus delbrueckii* LE™ strain. This highly active LAB strain was isolated from a natural dairy product. The *L. delbrueckii* LE form of *L. delbrueckii* exhibits strong immunomodulating qualities. It also works well alongside chemotherapy drugs and radiotherapy, is highly anti-mutagenic, and has good detoxification attributes. This strain also exhibits high antagonistic activity against pathogens.

TARGET APPLICATION: Perfect strain for special foods and supplements to maintain immune health and protect against the consequences of infectious diseases, support chronic states, and support all types of medical treatments.

FUNCITONAL CHARACTERISTICS AND EFFICACY

The LE strain assists the restoration and balancing of the microbiota and serves as a potent immune modulator that balances and normalizes non-specific reactions working through cellular immunity. This strain also has the ability to support the immune system function during chemotherapy, radiotherapy and toxic influences of different natures reducing endogenous intoxication. It is also effective in antagonistic functions against pathogenic and food spoilage microorganisms.

Digestive Health Functionality

Vivoflora's *Lactobacillus delbrueckii* LE™ has high levels of survival in the human intestine as well as high resistance to bile salts, gastrointestinal enzymes and acids and exhibits good adhesion properties in vivo. This strain also has the ability to restore integrity to gastrointestinal epithelial cells.

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Immune System Modulation

L. delbrueckii LE™ form of *L. delbrueckii* exhibits superior immune modulating properties. It affects innate and adaptive immunity through both non-specific and specific links thus controlling coordination of the immune response by TH1 and TH2 pathways depending upon the immune status of the subject. This strain demonstrates a high ability to induce specific antibody production and balances the human immune system by stimulation of the production of key cytokines IFNs, TNF, NK cells, IL-1, IL-2, and IL-6 for protection against infections and cancer cells. It also serves as an immune modulator that balances and normalizes non-specific reactions working through cell-mediated immunity and induces higher responses in the presence of pathogenic agents. It provides immune balancing (via suppression) with respect to chronic diseases, inflammation, and immune imbalance caused by different agents such as tumors. The LE strain thereby modulates immune response to both endogenous and exogenous pathogenic agents.

Anti-Mutagenic and Detoxification Properties

Vivoflora's *Lactobacillus delbrueckii* LE™ shows strong resistance to chemotherapy drugs and a high level of adhesion in their presence. This strain provides deep correction to immune imbalance, protection from all harmful impacts of chemotherapy and radiation, reduction of endogenous intoxication and suppression or blockage of TNF activity.

Protective Functionality

The LE strain demonstrates antagonistic activity against pathogenic and conditionally-pathogenic microbes to create a favorable environment for development of useful gastrointestinal microflora. In particular, it exhibits antagonistic activity against Gram Positive and Gram Negative pathogens including those found in hospital infections, post operative infections and complications as well as antagonistic activity against food spoilage organisms. The *L. delbrueckii* LE™ form of *Lactobacillus delbrueckii* also maintains antagonistic activity in the presence of some widely used antibiotics.

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CLINICAL STUDIES

The *L. delbrueckii* LE™ form of *L. delbrueckii* in probiotic composition with the *L. rhamnosus* LB3™ form of *L. rhamnosus* was clinically used for patients including children with various gastrointestinal disorders and immune system problems including allergic infections. This study demonstrated a 75-95% positive effect against gastrointestinal pathogens, Candida and viruses. This combination of strains normalized immune profiles and restored microflora and epithelial tissue. Clinical testing was done in the Russian State Medical University (Moscow), State Military Academy (St. Petersburg), Harkov Gastro-intestinal Hospital (Harkov, Ukraine), and Donetsk Medical University, Immunology Department (Donetsk, Ukraine).

The LE strain alone and in probiotic composition with Vivoflora's *L. rhamnosus* LB3™ strain was clinically used for patients with different otolaryngology infections, including Candida and viruses, digestion and immune problems with 85-95% positive clinical effect, restoration of normal microflora, and normalization of enzyme and immune profiles. Clinical testing was done in the Hospital of Institute of Otolaryngology Academy of Medical Sciences, Kiev, Ukraine, 2002-2006, State Program "New Probiotics for Otolaryngology".

STRAIN ORIGIN & HISTORY

Vivoflora's *Lactobacillus delbrueckii* LE™ strain was isolated from a natural dairy product.

STRAIN AUTHENTICITY & DEPOSIT

According to FAO/WHO, Vivoflora's *L. delbrueckii* LE™ form of *L. delbrueckii* has been identified as *Lactobacillus delbrueckii* subsp. *delbrueckii* by use of phenotype, carbohydrate utilization or fermentation profile, and genetic ribotype technique. This strain has been deposited in the Ukrainian Strain Collection of Industrial Microorganisms as *L. delbrueckii* subsp. *delbrueckii* IMV B-7037.

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SAFETY ASSESSMENT

A safety assessment has been performed for acute and chronic toxicity using rats and mice. The LD50 in acute testing was >20g/kg body mass. A culture of this strain is safe, non-toxic and has no embryotoxic, no mutagenic, no teratogenic and no carcinogenic effects. The *L. delbrueckii* LE™ form of *L. delbrueckii* has been used for various food applications in the United States and for medical application in the Ukraine. *Lactobacillus delbrueckii* is a strain that has been commonly used since prior to 1994 and its safe use in dietary supplements is FDA compliant under the Dietary Supplement Health and Education Act of 1994 (DSHEA).

LIST OF PUBLICATIONS

1. Report on clinical use of the probiotic cells *Lactobacillus delbrueckii* LE and their lysate. A.S Prylutsky, MD, PhD, *Clinical Immunology and Allergy Department, Donetsk State Medical University, 1999*
2. Savtsova Z.D., Shpylevaya S.I., Tarutinov V.I., Rogatskaya V.P., NMeniok T.A., Nikolsky I.S., Mosienko V.S., Shynkarenko L.M., Chekhun V.F. Immune correction by an Immunomodulator from *Lactobacillus delbrueckii* LE in a combined therapy of breast cancer at stages II and IV. *Oncology 2000; 22:211-214*
3. Shpylevaya S.I., Tarutinov V.I., Mosienko V.S., Rogatskaya V.P., Ponomarev I.O., Shynkarenko L.M., Chekhun V.F. Correction of leucopenia by a new probiotic immunomodulator *Lactobacillus delbrueckii* product in combined treatment of breast cancer. *Oncology, 2000; 2 (1-2):83-86*
4. D. Zabolotny, L. Shynkarenko, O.Melnikov, L. Volosevich, I.Zarytska, O.Goloborodko, G. Karpenko, O.Bolyska, D. Zabolotna . Application of the probiotic medication "Acidolor" in patients with chronic tonsillitis and evaluation of its efficacy; *Journal of ear, nose and throat diseases , №5, 2003, page.2-9*
5. L.Shynkarenko, N.Dehtyrenko. Research of the Chemotherapy drugs influence on Lactic Acid Bacteria cells. *Scientific news of the NTU "KPI", 2004,1 (33), pp.135-140*

6. Volska, L.Shynkarenko, I.Zarytska, D.Zabolotna. Study of the possibility of the using of the Lactobacilli for treatment and prevention of the Candida infections in ENT-organs. *Odessa medical Journal*, 2006, 4(96), pp.32-36

L. delbrueckii LE™ is a registered trademark of Vivolac Cultures Corporation.

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