

Children's ENT-Pro™

Target-Specific Probiotic Formulation with Lysozymes
Nutritional Support for Otolaryngeal Health

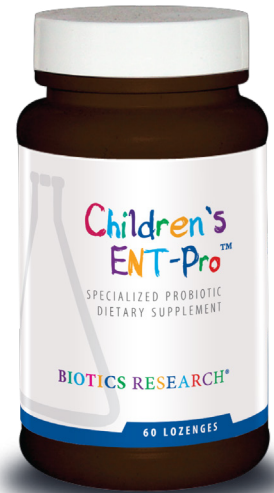
Children's ENT-Pro™ is a pleasant-tasting strawberry-flavored probiotic lozenge that supplies newly isolated *Lactobacillus delbrueckii* LE and *Lactobacillus rhamnosus* LB3 strains, along with *Lactobacillus plantarum* LM, *Bifidobacterium longum* and *Bifidobacterium bifidum*, combined to support otolaryngeal health in children.

Probiotics are classically defined as a "preparation of, or a product containing viable, defined microorganisms in sufficient numbers, which alter the microbiota in a compartment of the host, and exert beneficial health effects in the host". Traditionally, probiotics are used to influence the microbial balance specifically in the gastrointestinal tract, which is host to billions of diverse and metabolically active organisms. These microorganisms have been found to influence metabolic function, inform the immune system, protect against pathogens, affect brain function and even steer genetic expression through epigenetic mechanisms. Probiotics have played a key role in the competitive inhibition mechanism where the "good bacteria" outweigh the "bad bacteria," and theoretically shift the microbial balance towards benefitting the host's overall health.

However, with acute infections, such as those afflicting the ear, nose and throat areas in children, antibiotics are often prescribed in order to address the pathogens. In some cases of persistent infection, surgery may even become necessary to avoid further complications such as hearing loss. Otitis media (OM) is one of the most common diagnoses made by pediatricians. Other diagnoses affected by viral and bacterial pathogens within the otolaryngeal cavity include tonsillitis (inflammation of the pharyngeal tonsils), sinusitis, pharyngitis (sore throat), and inflammation of the adenoids.

In search of natural and potent ways to support otolaryngeal health, with no negative side effects, renowned microbiologist Liubov Sichel, PhD, created the target-specific probiotic formulation, **Children's ENT-Pro™**. Target-specific probiotic formulations are designed to promote the biological mechanisms that support the health of specific tissues and organs.

In this newer probiotic model, **Children's ENT-Pro™** provides a specific probiotic formula integrating targeted support for sinus structures and surrounding tissues. The strains selected for **Children's ENT-Pro™** have been shown to adhere to the cells of the oral cavity and promote immune-modulating qualities.⁽¹⁾



(800) 231-5777

6801 Biotics Research Drive • Rosenberg, TX 77471
biotics@bioticsresearch.com • www.bioticsresearch.com

These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

Unlike other probiotic strains targeting otolaryngeal health, such as *Streptococcus salivarius*, the strains found in **Children's ENT-Pro™** are not considered opportunistic pathogens, which can be detrimental under certain circumstances.⁽²⁾ Rather, they are safe and well-researched strains, exhibiting high levels of pathogen-specific activity and immune-modulating behavior. Safety assessments confirm the strains are non-toxic and have no embryotoxic, mutagenic, teratogenic or carcinogenic effects.

ENT Health Clinical Data

Clinical testing was performed in the Hospital of Institute of Otolaryngology Academy of Medical Sciences, Kiev, 2002-2006, for State Program "New Probiotics for Otolaryngology". Strains of *L. delbrueckii* LE and *L. rhamnosus* LB3, as well as combination blends, were found to demonstrate high levels of antagonistic activity towards the microbes most frequently found in chronic and recurring ENT infections. In addition to showing a high degree of adhesion to the mucous coat of the upper air passages, application of the formulation resulted in a statistically reliable increase of the number of tonsillar cells producing IgA, as well as increased activity of the natural cytotoxic tonsillar cells, and increased number of tonsillar cells with surface antigens CD25 and CD56.

Probiotic formulations based on these strains also induced a proficient immune response by TH1-type cytokines, inhibited fatty cellular infiltration of tonsils tissue, and stimulated progression of B-cell lymphocytes and high glycogen macrophages. It was observed that this probiotic formulation stimulated IFN up to 4.5-fold, induced production of the IL-4, increased IgG and IgA up to 2.5-fold, and intensified glycogen synthesis in phagocytes. *L. rhamnosus* LB3 demonstrated more effective activation of humoral immune response; whereas, *L. delbrueckii* LE showed mostly cell-mediated immune response.

In one study, tonsillar cells from patients with adenoid disease were cultivated with *L. rhamnosus* LB3. After four hours, *L. rhamnosus* LB3 had increased the number of cells with membrane antigen CD25 (activated cells), increased the number of IgA producers by 30%, and intensified the functional activity of the natural cytotoxic cells 3.4 times as much.

The specific combination of lactobacilli and bifidobacteria strains found in **Children's ENT-Pro™** also demonstrate antagonistic action in relation to a number of ENT pathogens, and help support a healthy immune response in their presence.

Table 1 Antagonistic Activity Against ENT Pathogens

Test-culture	Zone of growth inhibition, mm			
	<i>L. delbrueckii</i> subsp. <i>bulgaricus</i> 51	<i>L. delbrueckii</i> LE	<i>L.rhamnosus</i> LB3	<i>L. delbrueckii</i> NCDO 213
<i>Escherichia coli</i> M-17	20 ± 1	28 ± 1.2	32 ± 2	20 ± 1.4
<i>Enterobacter cloacea</i>	21 ± 1	26 ± 1.2	32 ± 1.8	18 ± 0.9
<i>Citrobacter freundii</i>	19 ± 1	25 ± 1.1	30 ± 1.1	18 ± 1
<i>Escherichia coli</i> k12	21 ± 0.9	28 ± 1	19 ± 1.2	18 ± 0.8
<i>Klebsiella pneumoniae</i> K-1	15 ± 0.8	29 ± 1	32 ± 1	15 ± 0.9
<i>Proteus vulgaris</i> 72	8 ± 0.5	12 ± 0.1	27 ± 0.6	18 ± 1
<i>Salmonella equiabortus</i> 202	40 ± 1.3	48 ± 3.2	45 ± 3.6	15 ± 3.9
<i>Salmonella typhimurium</i> 11	28 ± 1.1	35 ± 1.3	26 ± 1.9	27 ± 2.1
<i>Serratia marcescens</i> 10	39 ± 1.8	46 ± 3.1	45 ± 3.8	42 ± 3.8
<i>Pseudomonas aeruginosa</i> 103	16 ± 0.7	22 ± 1	36 ± 1	21 ± 1
<i>Pseudomonas alcaligenes</i> CC2655	17 ± 1	22 ± 1.2	29 ± 1	21 ± 1.4
<i>Micrococcus puogenes</i>	39 ± 2.1	46 ± 2.6	35 ± 3.4	35 ± 3.2
<i>Staphylococcus aureus</i> 209P	25 ± 2.1	33 ± 1.2	31 ± 2.4	21 ± 1.7
<i>Staphylococcus epidermidis</i>	18 ± 2.3	24 ± 1.1	28 ± 2	31 ± 2.3
<i>Candida albicans</i> 212	0	8 ± 0.6	32 ± 2.4	0

O. Volska, D. Zabolotna. Study of the mechanisms of antagonistic activity in different probiotic strains. Journal of ear, nose, and throat diseases, No3-c, 2003,p.164-165.

Children's ENT-Pro™ consists of probiotic strains that are resistant to gastric secretions, bile salts, gastrointestinal enzymes and acids, giving them very high survivability ratings. and are described as perfect strains to support optimal otolaryngeal immune health.⁽³⁾

Lysozymes

In addition to the probiotic strains, **Children's ENT-Pro™** includes lysozymes. A lysozyme is an enzyme often used to lyse bacterial cells by hydrolyzing the peptidoglycan in the cell walls.

Lysozymes, first discovered by Alexander Fleming in a search for something to slow bacterial growth, exhibit selective antibacterial properties for oral microorganisms, and are naturally found in the saliva and tears as part of the innate immune system⁴. Lysozymes are considered especially advantageous in the support of a healthy respiratory tract (US Patent 9,950,041), and have recently received Novel Food Status in the European Union (EU) 2018/991.

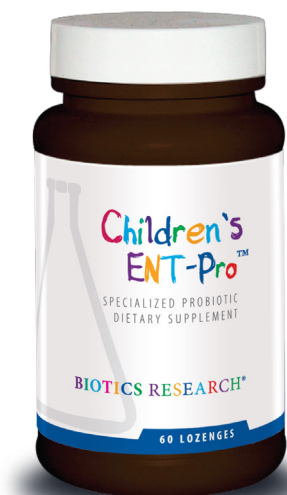
Children's ENT-Pro™

- Promotes the biological mechanisms that support otolaryngeal tissues and organs
- Adheres to oral cavity mucous coat
- Demonstrates high survivability under both acidic and alkaline environments
- Shows antagonist activity towards opportunistic microflora, including Candida strains
- Exhibits immuno-modulating effects
- Activates immunocompetent cells by CD25+, CD56+ antigens, NK cells, IFNs
- Stimulates production of B cell lymphocytes, IgA
- Demonstrate high clinical result with positive effect on the microbiocenosis of the upper air passages
- Possesses activating effect on a wide range of responders on tonsillar cells

Recommended Use:

- As a daily probiotic, take 1 lozenge per day.
- When needing extra immune support, take up to 4 lozenges per day.
- For best absorption, place under the tongue to dissolve. Hold in the oral cavity for about 60 seconds.
- Each **Children's ENT-Pro™** lozenge contains a minimum of 2 billion microorganisms.

Children's ENT-Pro™ is available in a 60-count bottle (#1145).



Supplement Facts

Serving Size: 1 Lozenge

	Amount Per Serving	% Daily Value
Proprietary blend	2 billion organisms	
Lactobacillus rhamnosus LB3*, Lactobacillus delbrueckii LE*, Lactobacillus plantarum LM*, Bifidobacterium longum*, Bifidobacterium bifidum*		
Lysozyme	10 mg	*
Fructooligosaccharides	25 mg	*

* Daily Value not established

Other ingredients: Mannitol, sorbitol, natural flavor, citric acid, modified cellulose gum, magnesium stearate and silica.

This product is gluten free.

RECOMMENDATION: One (1) lozenge each day as a dietary supplement or as otherwise directed by a healthcare professional.

Formulated to provide support for healthy EN&T function. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

CAUTION: May contain trace amounts of milk and egg protein.

KEEP OUT OF REACH OF CHILDREN

Store refrigerated.

Sealed with an imprinted safety seal for your protection.

Product # 1145 Rev. 09/18

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