

Managing allergic symptoms; hay fever and eczema

Worldwide, the prevalence of allergic diseases is rising dramatically in both developed and developing countries. In spite of this escalation, even in the developed world, treatment options for patients with allergic diseases are far from ideal.¹⁻³

Allergic diseases are caused by hypersensitivity of the immune system to harmful substances in the environment. Major allergic diseases include asthma, food allergies, allergic rhinitis [AR] and atopic dermatitis [AD] or eczema. Worldwide, AR currently affects between 10% and 30% of the population and studies indicate that prevalence rates are increasing. AD affects nowadays 15-30% of children and 2-10% of adults.⁴ Allergic diseases have a high morbidity, are responsible for a substantial proportion of health service use, and are accompanied by a severely reduced quality of life.⁵

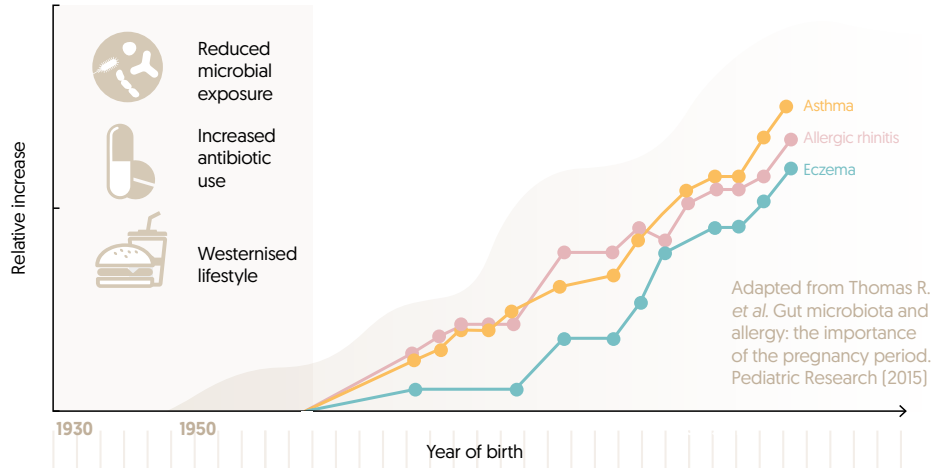


Figure 1: Major changes in microbial exposure in the first half of the century are believed to trigger the accelerating increase in allergic diseases.

It is not completely clear what triggers the dramatic increase in incidence of allergies, but many theories postulate the involvement of [Westernized] lifestyle, environment and [missing] microbes.^{6,7} Moreover, the World Allergy Organization and clinical studies reveal that a reduced biodiversity and alter-

ations in the composition of the gut and skin microbiota are associated with various inflammatory conditions, including asthma and allergy.⁸ Thus, a potential approach to manage allergic symptoms could be the administration of specifically selected probiotic strains.

Strain selection

Ecologic[®] ALLERGYCARE is a multispecies probiotic formulation consisting of 6 specially selected probiotic strains. Probiotic strains can exert health effects at different levels in the gut [see figure 2]. The probiotic strains of Ecologic[®] ALLERGYCARE have been selected to influence the immune system [level 3]. The strains have been screened *in vitro* for their capacity to:

- Modulate production of immunosuppressive cytokines by;
 - induction of IL-10 and IFN- γ
 - reduction of IL-4, IL-5 and IL-13.

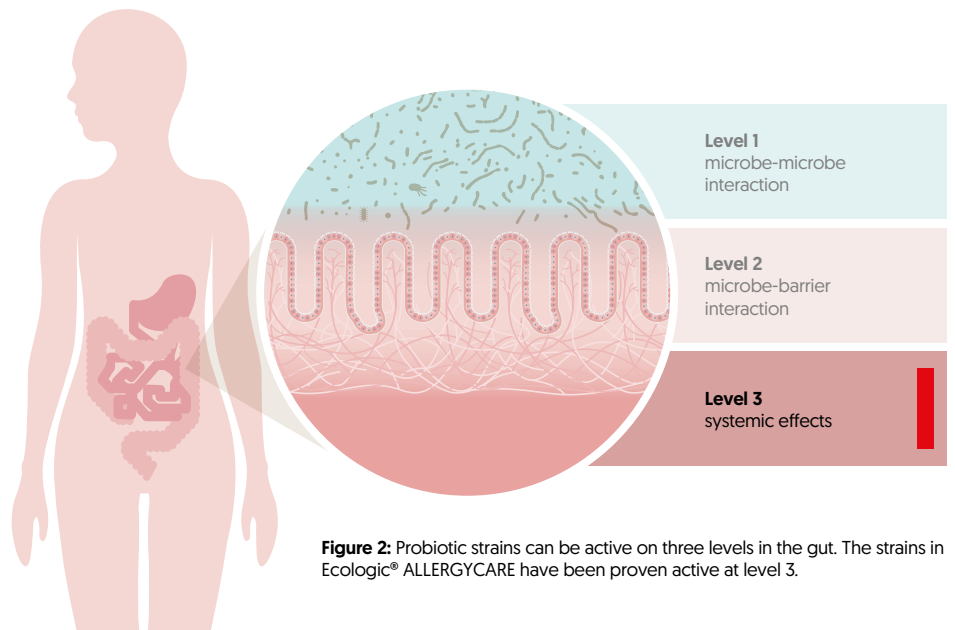


Figure 2: Probiotic strains can be active on three levels in the gut. The strains in Ecologic[®] ALLERGYCARE have been proven active at level 3.

Clinical evidence

The effect of Ecologic® ALLERGYCARE on AD symptoms has been tested in a double-blind, randomized, placebo-controlled human trial, performed by Harran University, Turkey⁹. Forty children between 1-13 years of age suffering from AD received 2x10⁹ CFU Ecologic® ALLERGYCARE or placebo twice daily for eight weeks. Both clinical and mechanistic effects were measured at baseline and at the end of the intervention period. **Ecologic® ALLERGYCARE significantly reduced the SCORing Atopic Dermatitis (SCORAD) index.**

[see figure 3]. These results are supported by the finding that total IgE levels were significantly dropped in the probiotic group, compared to the placebo group.

The effect of Ecologic® ALLERGYCARE on quality of life (QoL) in patients with AR has been tested in a clinical trial performed by Griffith University Australia^{10,11}. Forty hay fever patients received 2x10⁹ CFU Ecologic® ALLERGYCARE twice daily for eight weeks. Before and after the intervention period, QoL was determined

using the rhinitis quality of life questionnaire (RQLQ). During the intervention patients also recorded AR symptoms and medication use. **Ecologic® ALLERGYCARE significantly improved QoL in 63% of the patients** (meaningful improvement >0.7 decrease in the RQLQ, $p=0.005$). The average RQLQ score dropped from 2.83 at baseline to 1.66 at midpoint to 1.38 at week 8 [see figure 4]. In line with these findings, a trend towards reduction in AR symptoms and medication use was found.

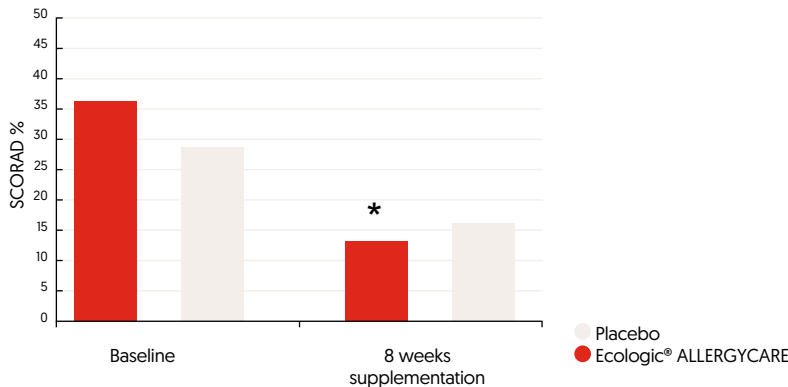


Figure 3: Changes in the SCORAD-index before and after the intervention. * Significant decrease, $p=0.005$.

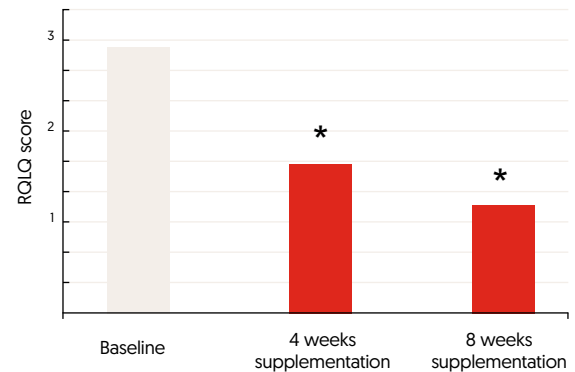






Figure 4: RQLQ scores during the intervention. * Significant decrease, $p=0.005$.

Formulation details

Indication	Managing allergic symptoms; hay fever and eczema.			
Colony forming units (CFU)	1 x 10 ⁹ CFU/gram.			
Bacterial strains and other active ingredients	<i>B. bifidum</i> W23 <i>B. lactis</i> W51	<i>L. acidophilus</i> W55 <i>L. casei</i> W56	<i>L. salivarius</i> W57 <i>L. lactis</i> W58	vitamin B2 and biotin.
PROBIOACT® Technology	 Carefully selected ingredients that contribute to stability (shelf-life), GI-survival and metabolic activity of the probiotic strains.			
Recommended daily dosage	2 grams, twice daily.			
Treatment period	For as long as desired/needed.			
Storage and stability	2 years stable at room temperature, no refrigeration needed.			
Available dosage forms	Dry powder which can be supplied as bulk or sachets, fully packed (with your design).			
Safety and Quality Profile	 	All probiotic strains have the Qualified Presumption of Safety (QPS) status ¹² . Winclove is a NSF International Certified GMP Facility for manufacturing dietary supplements and is ISO 22000:2005 certified for the development and production of pre-and probiotics.		
Marketing		Medically endorsed under private label on a co-branding basis. Co-branding enables our business partners to use the scientific data in their marketing communication.		
Health claims	Diverse approved health claims for vitamin B2 and biotin.			

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