



# PENTABIOCEL®

A VALID HELP FOR CELIAC DISEASE  
AND GLUTEN SENSITIVITY

**SACCO**  
system  
Supporting food culture & life

**Celiac disease (CD)** is an immune-mediated systemic disorder elicited by gluten and related prolamines (e.g. gliadin) in genetically susceptible individuals. The ingestion of gluten causes an immunological response that causes a chronic damage in the small intestine with morphological changes of the mucosa, atrophy of the villi and consequent malabsorption and inflammation. In the pathogenesis of celiac disease, factors such as: gastrointestinal infections, introduction of gluten during weaning, the quality and quantity of gluten taken with the diet and the development of a particular intestinal bacterial flora are involved.

The analysis of the intestinal microbiota suggest that it could play a prominent role in this pathology: in particular, in CD patients was found dysbiosis with a decrease of Bifidobacteria and Lactobacilli genera. To date the only treatment for CD is lifelong adherence to a gluten-free diet (GFD). However, the GFD does not restore the intestinal dysbiosis typical of these patients, in particular, the percentage of beneficial bacteria. It has surprisingly been found that **PENTABIOCEL®** a patented blend of Lactobacilli and Bifidobacteria, is able to improve markedly the irritable bowel-type intestinal symptoms in celiac patients.

## TECHNICAL INFORMATION

### IDENTIFICATION

all strains have been subjected to a total DNA extraction and a 16S rDNA sequence analysis

### SAFETY

included in EFSA QPS list  
(EFSA Journal 2017)

absence of investigated  
antibiotic resistance genes  
(EFSA Journal 2012;10(6):2740)

BSE/TSE free

GMO free

Colorant and allergen free  
(list of allergens in compliance with  
Reg. UE 1169/2011)

### SHELF LIFE

18 months at temperature  $<-18^{\circ}\text{C}$

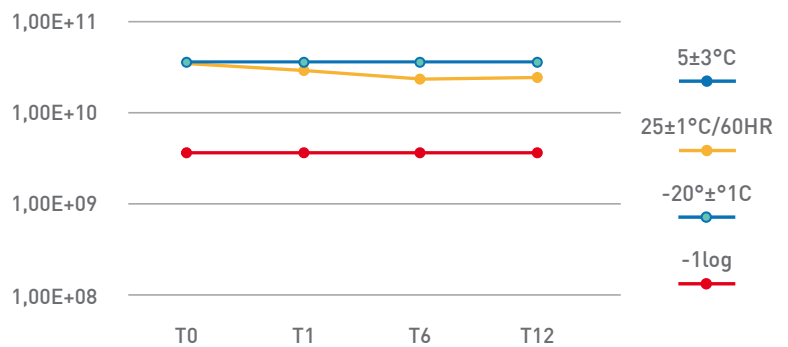
12 months at temperature  $5\pm 3^{\circ}\text{C}$

### STABILITY

Stability studied both on the blend and on the dosage form (sachet)

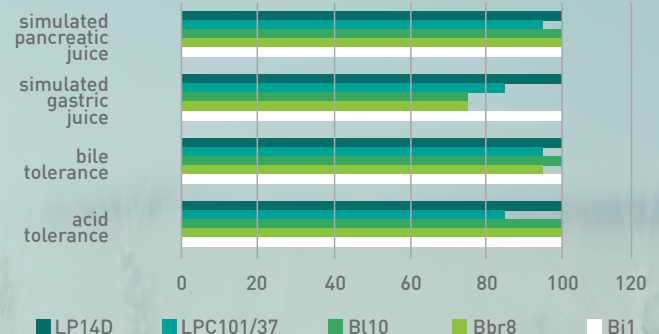
- Stable for 18 months at  $5\pm 3^{\circ}\text{C}$

#### STABILITY OF THE BLEND



\*for one batch of the dosage form the study was extended to 24 months at  $5\pm 3^{\circ}\text{C}$  showing a survival of 95%

## SURVIVAL DURING GASTROINTESTINAL TRANSIT



### PRODUCT COMPOSITION

PENTABIOCEL® is a blend of probiotic strains:

- *Lactobacillus paracasei* 101/37 (LMG P-17504)
- *Lactobacillus plantarum* 14D (CECT 4528)
- *Bifidobacterium breve* Bbr8 (LMG P-17501)
- *Bifidobacterium breve* BL10 (LMG P-17500)
- *Bifidobacterium animalis subsp lactis* Bi1 (LMG P-17502)

## HOW PROBIOTICS CAN CONTRIBUTE TO THE IMPROVEMENT OF CELIAC DISEASE?

- The probiotics has the ability to hydrolyze toxic gliadin polypeptides. (Western blot analysis)
- Reinforce microflora balance
- Protection against pathogenic microorganisms
- Increase in immune defenses
- Reinforce barrier effect

## CLINICAL TRIAL

PENTABIOCEL® can be used for the therapeutic treatment of intestinal symptomatology secondary to celiac disease.



- 58 PROBIOTICS
- 58 PLACEBO



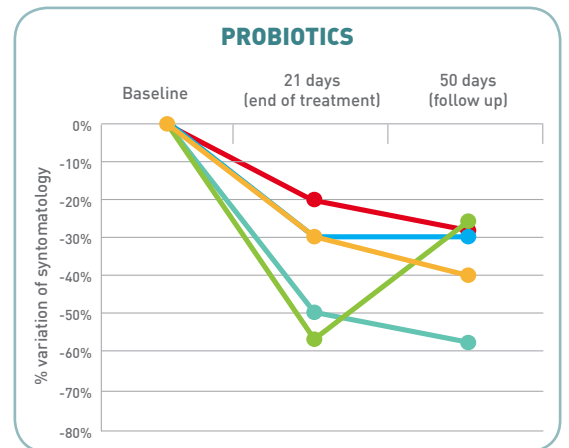
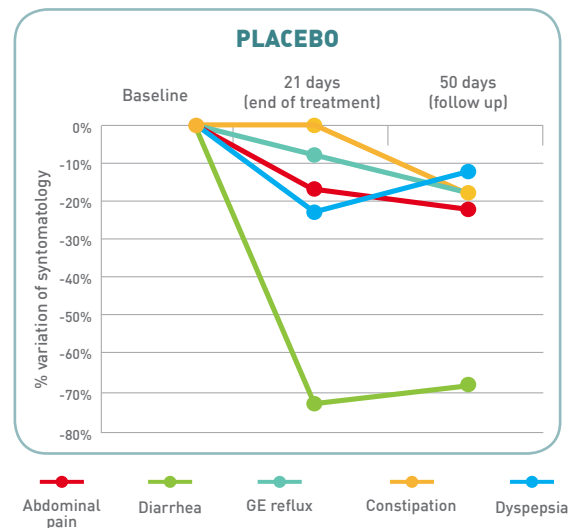
Daily dose



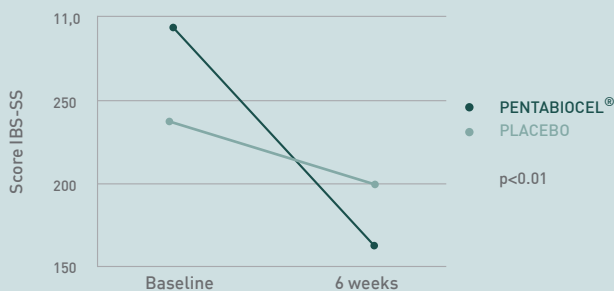
Intervention period

### DAILY DOSE (1 STICK)

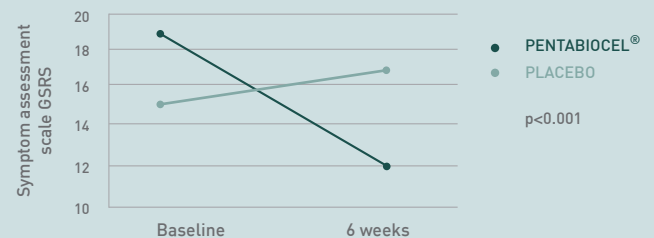
<i>L. paracasei</i> 101/37	5 E+09 CFU/2.5g
<i>L. plantarum</i> 14D	5 E+09 CFU/2.5g
<i>B. breve</i> BBR8	3.4 E+09 CFU/2.5g
<i>B. breve</i> BL10	3.4 E+09 CFU/2.5g
<i>B. animalis subsp lactis</i> Bi1	3.4 E+09 CFU/2.5g



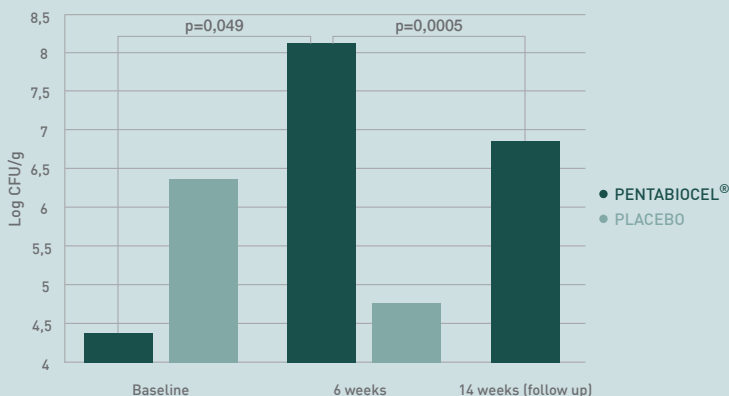
### IBS SEVERITY SCORE (IBS-SS)



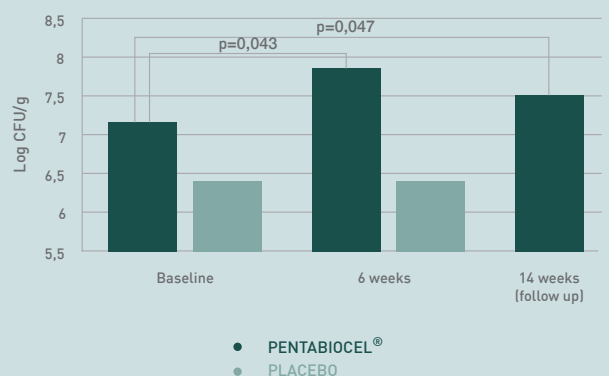
### GASTROINTESTINAL SYMPTOM RATING SCORE (GSRS)



### INCREASE OF *lactobacillus*



### INCREASE OF *bifidobacterium*



In collaboration with *Innovazione & Ricerca*



Download on  
Apple Store & Google Play

Sacco System is the new international biotech centre for innovation in nutraceutical and pharmaceutical products. Sacco System provides its customers with healthy, natural and functional products.

We can offer a flexible service, develop formulation into adopted dosage forms, toll manufacturing (from laboratory to pilot production) and partnership for the development, production and the sale of single or mix probiotic strains of property or patented.

saccosystem.com



# PENTABIOCEL®

A VALID HELP FOR CELIAC DISEASE  
AND GLUTEN SENSITIVITY



## REFERENCES

Cenit MC et al. Intestinal Microbiota and Celiac Disease: Cause, Consequence or Co-Evolution? Nutrients 2015; 7: 6900-6923

De Palma G et al. Effects of gluten-free diet on gut microbiota and immune function in healthy adult human subjects. Br J Nutr 2009; 102:1154-1160

De Angelis M et al. VSL3# probiotic preparation has the capacity to hydrolyze gliadin polypeptides responsible for Celiac sprue. Biochim Biophys Acta 2006; 1762(1): 80-93

Smecuol E et al. Exploratory, Randomized, Double-blind, Placebo-controlled Study on the Effects of Bifidobacterium infantis Natren Life start strain super strain in active celiac disease. J Clin Gastroenterol 2013; 47(2):139-47

Francavilla R et al. Efficacy of Multispecies Probiotic Supplementation in Irritable Bowel Syndrome Associated with Celiac Disease: from Clinical to Microbiological Analysis a Randomized, Double-Blind, Placebo Controlled Trial. Submitted to J Clin Gastroenterol



Download on  
Apple Store & Google Play

Sacco System is the new international biotech centre for innovation in nutraceutical and pharmaceutical products. Sacco System provides its customers with healthy, natural and functional products. We can offer a flexible service, develop formulation into adopted dosage forms, toll manufacturing (from laboratory to pilot production) and partnership for the development, production and the sale of single or mix probiotic strains of property or patented.

[saccosystem.com](http://saccosystem.com)