

DEPARTMENTS ◀◀

Ingredients & Products

forms and during storage before consumption. The spores are thermostable as against viable *L. acidophilus* cells which may not withstand lyophilization

- survive in gastric secretions and bile of the upper digestive tract and reach the intestine safely
- settle in the digestive tract and produce enough lactic acid and other antagonistic substances to inhibit the growth of pathogenic bacteria
- being sporulated, they germinate under favorable conditions and produce sufficient viable cells which proliferate and perform vital healthful functions as described earlier. In addition, *L. sporogenes* spores are semi-resident and are slowly excreted out of the body (7 days after discontinuation of administration).

For information

Sabinsa

tel +49 6103 27011-11

email sabinsa.europe@sabinsa.com

web www.sabinsa.com/leangard

Sabinsa in a nutshell

Sabinsa Corporation is a manufacturer and supplier of herbal extracts, cosmetics, minerals and specialty fine chemicals.

Celebrating its 20th year servicing the natural products industry, Sabinsa's mission is to provide alternative and complementary natural products for human nutrition and wellbeing. Over the past several years, the company has brought to market more than 50 standardized botanical extracts and privately funded several clinical studies. Sabinsa has six state-of-the-art manufacturing facilities in India dedicated to the production of herbal extracts, phytochemicals, biotech ingredients and supercritical extracts. In the U.S., the company in Payson, Utah, which provides cutting-edge capabilities for the development of capsules, tablets, bulk custom pre-mixes, drum-to-hopper blends, stick packs and powdered drinks.



ECOLOGIC®825

A multispecies probiotic food supplement for IBD
by **Winlove Bio Industries BV**

Inflammatory Bowel Disease (IBD) is the collective name for a group of severe gastrointestinal disorders, including mainly Crohn's disease (CD) and ulcerative colitis (UC). IBD is a chronic, relapsing immunological disorder associated with uncontrolled inflammation within the gastro-intestinal tract, which may lead to an increased risk of colorectal cancer later in life. In UC, inflammation affects the inner layer (the mucosa) of the intestinal wall of the large intestine whereas in CD, it may affect all layers of the intestinal wall of the entire gastro-intestinal tract from mouth to anus.

It is widely believed that the intestinal bacteria can induce and sustain inflammation in genetically susceptible hosts with defective immunoregulatory mechanisms. The normal composition of the enteric microbiota shows several changes in IBD. An altered balance of beneficial versus pathogenic microbial species could lead to a pro-inflammatory luminal milieu, which may initiate chronic intestinal inflammation in a susceptible host. Lower numbers of lactobacilli, and higher numbers of coliforms and bacteroides have been found, and these are thought to be responsible for the development of inflammation and the subsequent immune response. Inflammation and lesions generally occur in the ileum and colon, which are the regions with the highest bacterial concentrations. High mucosal bacteria counts are reported in patients with bowel inflammation, and counts increase with the severity of disease, in both inflamed and non-inflamed tissue.

Since it is reasonable to assume that the intestinal microbiota plays a role in IBD, probiotics are being evaluated as an alternative and safer means of manipulating the microflora in chronic inflammation. Indeed, there is evidence that certain probiotics have a beneficial effect in UC, but the evidence in CD is poor.

Open pilot study

Study design

To estimate the effectiveness of Ecologic 825, an open pilot study was conducted on 62 IBD (both UC and CD) patients. The patients took 3g of the probiotic food supplement on a daily basis for 2 months before breakfast or before bedtime.

Questionnaires were designed by Winlove Bio Industries. The patients had to fill in 3 questionnaires in total; one questionnaire prior to the pilot study (T=0), one after 1 month (T=1), and another after 2 months (T=2). The first questionnaire contained questions about personal details, the type and progress

DEPARTMENTS

Ingredients & Products

of disease, the experienced symptoms, diet and medication. The second and third questionnaires contained questions about general well being, experienced benefits of the product, and decrease in common symptoms, diet, and medication during the previous month. There were no exclusion criteria, and the patients continued on their usual medication and/or diet.

After the first month, 60 patients (40 UC, 20 CD patients) continued with the pilot and the third questionnaire was returned by 54 patients (37 UC, 17 CD patients).

Composition of Ecologic®825

Ecologic®825 is a multispecies probiotic food supplement consisting of 10 probiotic strains: *Bifidobacterium bifidum*, *B. infantis*, *B. lactis*, *B. longum*, *Lactobacillus acidophilus*, *L. casei*, *L. paracasei*, *L. salivarius*, *L. plantarum*, and *Lactococcus lactis*, with a total cell count of 2.5×10^9 colony forming units (cfu) per gram. This product was specially designed for use in severe gastrointestinal disorders.

Results

Symptoms

The first questionnaire showed that 93 and 85% of the UC and CD patients, respectively, had flare-ups during the 2 years prior to this pilot, which indicates that the study group was still in a semi-active state of disease with accompanying symptoms. The most common symptoms that occur in these inflammatory diseases were investigated. From the patients with symptoms, the progress was examined after 1 and 2 months, and results are summarised in Figure 1. Patients who showed a decrease within the first month and no change within the second month, were scored as an overall decrease after 2 months.

All symptoms occurred equally in both UC and CD, except rectal bleeding. The latter was experienced by 25% of the patients with CD, compared to 60% of the UC patients. This low incidence explains why CD patients did not have any reduction in

this symptom.

Diarrhoea and bloating were the most common symptoms, and between 70 and 90% of all patients suffers from this. Diarrhoea was mostly decreased in UC patients (56% vs. 33% in CD patients). Bloating was reduced by 47% in UC and 33% in CD patients.

Abdominal pain is another widespread symptom which occurred in 60 to 70% of all patients. This was reduced by 65% in UC patients and 33% in CD patients.

Cramps were experienced by approximately 43% of all patients. The decline of this symptom in CD patients was 33% and 57% in UC patients.

30 to 40% of all patients normally show constipation. A decrease was experienced in 43 and 58% of the CD and UC patients, respectively.

General well being, diet and medication

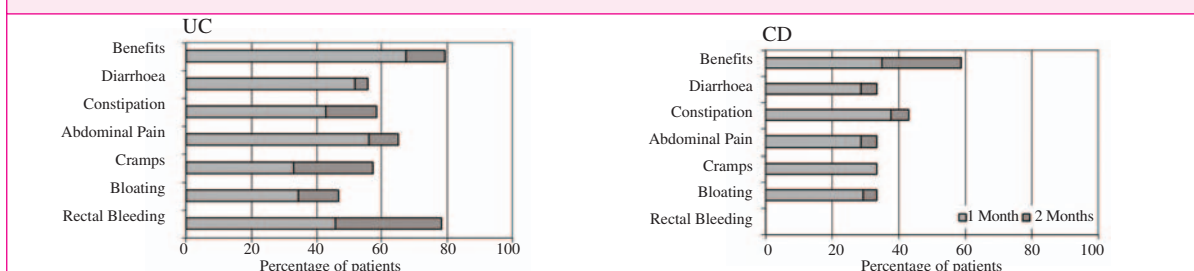
The general well being of all participants was monitored after 1 and 2 months. As can be expected from the results above, the general well being was increased in the UC group by 52 and 56% after 1 and 2 months, respectively. In the CD group, this was 25 and 41%.

50% of the UC patients and 30% of the CD patients followed a special diet with a lot of variation in diets, e.g. dairy free diets, gluten free diets, low meat great wheat diets. It was asked if and in which way the patients changed their diet during this study. By the end of the pilot, 82% of the UC patients with special diets changed their diet, mostly into a less restrictive regime. This change was observed in only 6 to 20% of the CD patients.

57 and 50% of the UC and CD patients, respectively, were familiar with probiotics in general and had been consuming them for at least once a month prior to this pilot. Participating patients did not have to alter their diet, but quitting the probiotic intake was desirable, and most people did.

88 and 70% of the UC and CD group were using food supplements such as vitamins, minerals, herbs and fatty acids. The intake of these supplements did not alter during the pilot.

Figure 1 Percentage of UC and CD patients experiencing benefits and reductions in symptoms within 1 and 2 months of using Ecologic 825



DEPARTMENTS ◀◀

Ingredients & Products

More than half of the patients were using medicines for their inflammatory diseases (64 and 60% in UC and CD patients respectively). 25 and 10% of these UC and CD patients altered their medication (under medical supervision), mostly into a lower dose of their current medication. 25% of the CD patients used antibiotics during the first month.

Subjective benefits

68% of the UC patients indicated that they experienced benefits of the product within the first month. After 2 months, this percentage increased to 77%. The outcome of this aspect was slightly lower in the CD group, with 35% within the first month and 59% within 2 months.

Conclusions and perspectives

Ecologic 825 has a positive influence on patients with inflammatory bowel disease. This is especially seen in patients with UC, where 77% of the patients felt better after using this probiotic food supplement for 2 months. 68% already experienced these benefits within the first month. In patients with CD, the benefits appeared after 1 month in 35% of the patients, and 59% experienced benefits after 2 months.

The reduction in symptoms is higher in UC than in CD. This decrease stabilises in CD after the first month, but in UC a further improvement can be seen in the second month. The general well being of the patients increased by 56% in UC and 41% in CD. Ecologic 825 could thus be useful in IBD patients, especially UC patients..

Recommended Use

It can be recommended for all patients with inflammatory bowel disease, especially for patients with ulcerative colitis, to use this probiotic food supplement to increase their general well being. Patients should take it on a daily base, basis their normal treatment.

For information

L. Mulder,
Winlove Bio Industries BV,
Amsterdam, The Netherlands
tel +31(0) 20. 435 0235
email Linda.mulder@winlove.nl
www winlove.nl
www ecologic.eu.com

Marianne Fjordgård,
Kost & Velvaere, Grinsted, Denmark
tel +45 75 31.0123
email Fjordgaard@sund-kost.dk

Winlove Bio Industries BV in a nutshell

Winlove develops and produces effective and scientifically proven probiotic food supplements for B2B pharma- and nutraceutical marketing companies worldwide. Besides, Winlove is investing in research in the area of probiotics and gut health.

Kost & Velvaere in a nutshell

Kost & Velvaere is a company who gives nutritional and supplementary advice.

Ecologic[®] 825

Developed and produced by

www.winlove.com

www.ecologic.eu.com

W I N C L O V E
B I O I N D U S T R I E S B V