LACTOBAC® POWDER
LACTOBAC® CAPSULES

UNIQUE INTESTINAL HEALTH PRODUCT/REGISTERED TRADE MARK PROTECTED/RAPID RESTORATION OF NORMAL GUT FLORA/HUMAN STRAIN PROBIOTIC

General Description

LACTOBAC® CAPSULES provide an astonishing 44.5 billion organisms, or colony forming units (CFU), per dose, making it one of the most powerful probiotic supplements available. When swift recolonisation and implantation of gut flora is required (in conditions associated with the long term use of antibiotics and the contraceptive pill especially) the higher dose of LACTOBAC® CAPSULES make it a potent clinical ally. Each LACTOBAC® CAPSULE contains *Lactobacillus rhamnosus* and *Bifidobacterium longum*, two of the most important probiotic species for the human intestinal microecology. Taking Lactobac® Capsules at the same time as antibiotics will give the best chance of minimising damage to naturally occurring microflora.

Product Features and Highlights

The strains of *Lactobacillus rhamnosus* and *Bifidobacterium longum* are not only compatible in the gastrointestinal system, but are also considered to be two of the superior strains of probiotics for the human system. For example, in infants, *Lactobacillus rhamnosus* not only inhibits early intestinal infections but also assists the implantation of bifidobacteria by the creation of anaerobic conditions in the colon.

Other studies have shown that LACTOBAC® is the most reliable probiotic combination for immediate bowel recolonisation.

Active Ingredients

LACTOBAC® POWDER
Each 5 ml medicinal spoon (3 g) contains:
Human strain *Lactobacillus rhamnonsus* 14.25 billion CFU
Bifidobacteria longum 0.75 billion CFU
Totalling 15 billion CFU per 3 g dose

LACTOBAC® CAPSULES
Each capsule contains:
Human strain *Lactobacillus rhamnonsus* 40 billion CFU
Bifidobacteria longum 4.5 billion CFU
Totalling 44.5 billion CFU per capsule

Dosage

Recommended adult dose: Take 30 minutes before a meal.

Adults: Take 1 capsule daily.

Description

Dietary supplement of dairy-free *Lactobacillus rhamnosus* and *Bifidobacteria longum*. Low allergy exipients. Free from added salt, yeasts, gluten, wheat, dairy products, preservatives, artificial colours and flavours.

Advantages of Lactobac Capsules

- 1 capsule is equivalent to 8.9 grams of free powder
- Convenience and ease of administration
- Portability
- Less weight
- Less volume
- Non messy
- Accuracy of dose (determining correct dose has been difficult in powder form for some people)
- 100% vegetable gelatin capsule

When do I use a powder instead of a capsule?

- Powdered form is more appropriate for children
- The elderly
- When using probiotics added to food (non-detectable dosing)
- When frequent doses are required in acute conditions (transient gastrointestinal symptoms, 'food poisoning' etc.)
- When used topically or as a douche

Indications

- Aids or assists in the treatment of diarrhoea
- Aids digestion.
- Helps maintain healthy digestive function.
- Aids or assists in the relief of flatulence
- Relief of the symptoms/pain/discomfort of gastritis
- Relief of indigestion
- Aids, assists or helps in the maintenance or improvement of general well-being
- Restore bowel micro-flora after antibiotics, while using the contraceptive pill, or to assist when the diet is inadequate
- Relieves bloating
- Can increase tolerance in food-sensitive individuals
- Can stimulate digestion
- Assists in the treatment of heartburn

Potential Uses

When appropriately prescribed, the active ingredients in LACTOBAC® may assist patients suffering from the following conditions. Note that this statement does not imply or make a claim for a cure for these disorders. The use of LACTOBAC® POWDER should be based on published and relevant scientific and clinical data for each condition.

- Acne (some forms)
- Antibiotic use
- Atopic conditions
- Candida (mild)
- Chronic fatigue syndrome
- Colic
- Constipation
- Dental caries
- Diverticulitis
- Diarrhoea
- Detoxification
- Flatulence
- Gall bladder disease
- Gastroenteritis
- Gut dysbiosis
- High blood cholesterol
- Improves liver function
- Irritable bowel syndrome
- Oral contraceptive use
- Toxic bowel syndrome
- Dysbiosis in chemotherapy and radiotherapy patients

General Information:
A healthy gastrointestinal tract with adequate mucous production and appropriate bacterial colonization prevents the overgrowth of pathogenic bacteria, modulates disease processes, and prevents widespread inflammatory disorders. [1]

A complex community of microorganisms inhabits the gastrointestinal tract, the colon being the main site of microbial colonization. The indigenous microflora are considered to be composed of more than 500 different species of bacteria, a complex ecosystem. The quantity and variety of flora change within distinct areas of the gastrointestinal tract depending upon

pH, oxygen availability, characteristics of coexisting flora, mucosal attachment sites, peristaltic activity, enteric secretions and the oxidation-reduction potential of the surrounding area. [2]

The main function of the gut flora, from the host's point of view, is to prevent colonization by potential pathogens. It does so by efficiently out competing invading pathogens for ecological niches and metabolic substrates. Microbial metabolism also serves as an important source of energy for the gut wall, providing up to 50% of the daily energy requirements of colonocytes by fermentation of carbohydrates to organic acids, mainly butyrate. [3]

Butyrate is the most important of the short-chain fatty acids (SCFAs), and is the main energy source for the cells that line the colon. Adequate amounts of butyrate are necessary for healthy metabolism and protection of the colonic mucosa. [4]

A number of factors can disrupt the delicate gut microbial balance. These include stress, poor diet, illness, ingestion of antibiotics and/or medicines, harmful environmental conditions, chemotherapy and chronic disease [eg colon cancer and inflammatory bowel disease (IBD)].

The current interest in probiotic therapy is considerable. The evidence for the efficacy of probiotic therapy in a number of conditions, particularly those of the gastrointestinal system, is accumulating. This applies not only to the gastrointestinal system, but also to a number of conditions where gut dysbiosis is an important underlying aetiological or aggravating factor (eg acne, migraine, constipation, food allergy, some autoimmune disorders and chronic fatigue syndrome).

A significant number of research studies and trials have highlighted the fact that there are a number of different probiotic strains with significantly different actions, properties and characteristics. Even strains of bacteria within the same species can differ significantly from each other, and if manufactured by different methods, will have different properties and stability. As a result, the modes of action of various probiotics are under extensive investigation. [5]

When choosing probiotics, the main selection criteria include:

- Ability to resist degradation by bile and gastric acids
- Capable of successful implantation in the intestinal tract
- Stability of numbers and characteristics
- Colonisation potential
- Survival in situ
- The safety and efficacy of the strain must be validated by clinical trials, including research with humans

Mechanism of Action

Lactobacillus rhamnosus and *Bifidobacterium longum* are potent biotherapeutic agents that are used to maintain and restore normal intestinal microflora. The bacteria are thought to exert their pharmacological effects through a variety of actions:

- Modulating the immune system, increasing the production of antibodies, mobilizing macrophages, lymphocytes and other cells of the immune response system
- Increasing mucin production in the intestine, thereby providing local protection as well as enhancing the innate immune response
- Direct adhesion to intestinal epithelial cells and production of antimicrobial substances
- Acidification of the intestinal lumen creating an unsuitable environment for pathogenic micro-organisms while allowing indigenous lactobacilli and bifidobacteria to proliferate
- Suppressing the activity of toxic and carcinogenic amine-producing enzymes associated with unfavourable intestinal flora

Pharmacodynamics and Pharmacokinetics

The quality of the bacterial strain in probiotics alone is not enough to ensure their effectiveness. Research has shown that varying the medium in which probiotics are delivered can alter their ability to influence microflora and be absorbed by the body. [6]

Orally administered *L. rhamnosus* and *B. longum* are rapidly transported to the intestine. They live in the intestine from 24 hours to 30 days, and normally, they do not cross the intestinal epithelial barrier. There is no evidence to suggest that live bacteria are absorbed or metabolised by human epithelial cells. The bacteria may or may not reproduce themselves in the intestine and are passed out of the body with normal bowel movements. The bacteria can be inadvertently spread from the intestine to the urogenital and oral cavities, but this does not pose a health risk; in fact it is an additional benefit

Lactobacillus rhamnosus

It is only recently that *Lactobacillus rhamnosus* has been recognised as a species. Previously it was known as *Lactobacillus acidophilus*, then *Lactobacillus casei*, and later *Lactobacillus casei* subsp. *rhamnosus*. [7]

Lactobacillus rhamnosus is found in a large variety of natural substrates and in the vagina and digestive tract of humans and animals. It is considered to be one of the most important lactobacilli in its application to a number of conditions.

Resistant to bile and gastric acids and capable of successful implantation in the intestinal tract, *Lactobacillus rhamnosus* has several important functions, [6, 8-12] including:

- Coating the intestinal mucosa and protection against invasion of pathogenic bacteria and prevention of diseases caused by intestinal infections.
- Hydrolysis of lactose and reduction of lactose intolerance
- Supports detoxification and immune function during pregnancy, and reduces the incidence of atopy and allergy in the infant
- Inhibition of *Helicobactor pylori* and therefore important in the prevention of peptic ulcer
- Contribution to intestinal peristalsis and elimination of harmful amines derived from amino acids
- Limiting the action of putrefactive microbes, thus controlling production of toxins and their noxious effects

In infants, *Lactobacillus rhamnosus* can inhibit early intestinal infections by pathogenic streptococci, prevent chronic diarrhoea, supply beneficial lactic flora and help implantation of bifidobacteria by the creation of anaerobic conditions in the colon. *L. rhamnosus* not only colonizes, acidifies and protects the small intestine, it can also rapidly invade the large intestine, inhibit the growth of streptococci and clostridia, create anaerobic conditions and produce the biologically desirable L-(+)-lactic acid.

Regular use of *Lactobacillus rhamnosus* is also recommended for the elderly, who require a high level of protection of their digestive tract for optimal nutrition and health. In older people, there tends to be a reduced number of lactobacilli and bifidobacteria. Toxins from putrefaction and infections may

therefore develop more intensely and may contribute to the development of poor colon health.

Lactobacillus rhamnosus has shown interesting immunological properties. Several researchers, who have studied antitumoral activity and activation of immunity, report increased immunity through use of lactic acid bacteria. The administration of *L. rhamnosus* increases resistance to microbial and viral infections. This is due partly to increased levels of immunoglobulins IgG [3] and direct activation of macrophages. Partial resistance to viruses may derive from their absorption on cellular walls of *L. rhamnosus*.

It has been shown that there was a significant extension of survival time in cases of infections by *Listeria monocytogenes* in mice injected with the cellular walls of *L. rhamnosus*. Cellular walls of other lactobacilli have not produced the same protection.

Anti-listeria activity of the cell walls of *L. rhamnosus* may be caused by substances specific to that species. *L. rhamnosus* contains rhamnose in its membrane. Yokokura [13] has investigated the phage receptor material in *L. rhamnosus* cell walls and has demonstrated the effect of rhamnose on phage adsorption on the cell wall.

L. rhamnosus, along with other lactobacillus strains, was tested in an in vitro model of enterohemorrhagic *Escherichia coli* (EHEC) infection of a human colon epithelial cell line. While the adhesion and colonization of EHEC was not affected by any of the lactobacillus strains tested, the internalisation of EHEC into the cell line was markedly suppressed by *L. rhamnosus*, though not by others. The fact that *L. rhamnosus* showed outstanding potential for adhering to the colon epithelial cell line, compared with other strains, suggested that an avid interaction between *L. rhamnosus* and the host cell might modulate intra-cellular events responsible for the internalisation of EHEC. [14]

Bifidobacteria and Their Therapeutic Effects

Bifidobacteria dominate the flora of the large intestine. Like lactobacilli, bifidobacteria ferment several sugars, especially lactose and its components glucose and galactose. However, while lactobacilli ferment those sugars exclusively into lactic acid (homofermentative) or into lactic acid and other products including gas (heterofermentative), bifidobacteria ferment sugars into acetic and lactic acids in the proportion of 3:1 and do not produce gas. This metabolic pathway is specific and is named the bifidus path.

The genus *Bifidobacterium* includes approximately 30 closely related species. The species of bifidobacteria which are most prevalent in the colon of infants are *Bifidobacterium breve*, *B. longum* and *B. infantis*. [15]

Bifidobacteria lower the pH of faeces and keep putrefactive bacteria in check. In the presence of the bifidus factors, they produce L-(+)-lactic, acetic and traces of formic acids which lower the pH from 7.0 to 5.0, thus inhibiting pathogenic strains of Escherichia coli and infections produced by *Clostridium difficile* and *Clostridium perfringens*.

Bifidobacteria are sensitive to wide spectrum antibiotics and to those which are potent against gram-positive bacteria. However, they often limit their side effects, such as nausea and diarrhoea. In a well-controlled experiment, Colombel and associates [16] treated 10 volunteers with erythromycin administered orally and yoghurt containing *B. longum*. The stool weight and number, the presence of abdominal discomfort and the number of clostridium spores were noted. The simultaneous intake of yoghurt containing *B. longum* with erythromycin reduced the frequency of gastrointestinal disorders and reduced the clostridial spore count. The placebo yoghurt had no effect. This demonstrates that *Bifidobacterium longum* can re-establish the normal flora.

Another study by Schell et al, [17] established that the genome sequence of *Bifidobacterium longum* reflects its adaptation to the gastrointestinal tract. Bioinformatic analysis revealed several physiological traits that could partially explain the successful adaptation of this bacterium to the colon. An unexpectedly large number of the predicted proteins appeared to be specialized for catabolism of a variety of oligosaccharides. This ability to scavenge from a large variety of nutrients likely contributes to the competitiveness and persistence of bifidobacteria in the colon.

In a one month double blinded randomised controlled trial, 18 patients with active ulcerative colitis were treated with a *Bifidobacterium longum*, and a prebiotic. Compared with placebo, the active treatment group showed a significant reduction in proinflammatory cytokines and regeneration of epithelial tissue. [18]

Cautions

There are no negative indications for the use of these strains in infants and children. However, there are some groups (adults and children) who should be closely monitored during the administration of probiotic therapy. Abscesses as a result of bacterial overgrowth, have been reported in susceptible individuals for some probiotic preparations. Live bacterial supplements should not be consumed by severely immunosuppressed individuals without medical supervision. Severely immunosuppressed patients could include, but are not limited to, those undergoing chemotherapy, those who are on medication to suppress graft or organ rejection, and those in the latter stages of AIDs.

Other patients at risk include diabetics and those with pancreatic dysfunction. Live probiotic preparations may reduce insulin-dependancy in some diabetics. Direct application of live probiotic preparations to open wounds should also be avoided.

Side-Effects and Adverse Reactions

Some individuals may experience a slight increase in intestinal gas and bloating in the first week of treatment. The advice is to start with a low dose and increase gradually.

No adverse reactions have been reported to date.

Complementary Considerations/Companion Formulae

Liver Formula, Formula 33/33SE Forte, Formula SF88, Isofem, NervAsyst, Marine Oil – Marine Oil/EPO.

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