ProDURA® Overview

Health Benefits of the Probiotic ProDURA® *Bacillus coagulans*

Most probiotics have a relatively short, unstable shelf life and are not always amenable to formulating in other products for this reason. Spore-forming probiotic bacteria are bacillus species that can overcome this problem because the spore itself is a protective encasement that allows almost indefinite storage until it is ready to be consumed and can survive transit through the stomach intact (Ngo, 2000).

ProDURA *Bacillus coagulans* is a spore-forming bacterium that is stable at room temperature for up to three years' storage and is activated only with the proper conditions of heat, pH, and moisture found in the large intestine. It is better able to survive extreme environmental conditions of processing, shipping, and storage, as well as changes in chemical environment of the digestive tract.

Numerous health benefits

ProDURA has many of the same health benefits of most non-spore probiotics such as *Lactobacillus acidophilus*: the ability to inhibit *E. coli* and other pathogenic bacteria that are vancomycin-resistant (Donskey, 2001); lower total cholesterol and raise HDL (Sudha, 2011); reduce lactose intolerance; promote healthy growth of animals (piglets); and reduce the incidence of infections to provide an alternative to the overuse of antibiotics in animal feed (Adami, 1998; Cavazonni, 1998). In addition, ProDURA has been used to treat bacterial vaginosis and diarrhea (Sudha, 2011).

Cardiovascular health

For cardiovascular health, ProDURA produces a positive impact by improving lipid status. A study evaluated the effect of a *Bacillus coagulans* strain, Unique IS-2 (ProDURA), on serum lipids with 30 patients with hyperlipidemia (serum cholesterol levels of more than 200mg/dL). Those who were given 20 x 10^9 bacteria had reductions in total cholesterol of 14% and LDL of 0.8%, with an increase in HDL cholesterol levels of 3.6% (Sudha, Radkar, 2011).

Reduction in antibiotic-resistant intestinal pathogens

Vancomycin-resistant enterococci (VRE) have become an important pathogen that has emerged in hospital-transmitted infections during the past decade, and intestinal colonization is an important source for transmission of VRE, which may persist for months. VRE can cause intestinal infection with symptoms of diarrhea. Infected patients are a potential source for spread to other patients. No effective therapies are available to decrease the amount or duration of intestinal colonization, and antibiotics active against VRE, such as bacitracin, have been shown to have only a temporary effect on VRE colonization (Weinstein et al. 1999). A study conducted to determine the effect of ProDURA on stool colonization of VRE was found to reduce the density of colonization for one of three VRE strains tested. Oral bacitracin was administered to mice colonized with one of the VRE strains as a comparison (Donskey, 2001).

Animal health and antibiotic replacement

Bacillus coagulans as a probiotic may represent an alternative to antibiotics, according to a study performed on piglets. When the animals were fed a diet without any additive, for those given a diet that contained *Bacillus coagulans* CNCM I-1061 as probiotic, and in animals fed a diet that contained the antibiotic Zn-bacitracin, the numbers of enterococci (especially fecal coliforms) showed a decrease over time with the probiotic, more so than with the antibiotic. Daily administration of *B. coagulans* allowed this bacterium to integrate into the enteric microflora, where it seemed to show a positive effect of reducing levels of enterococci and fecal coliforms (Adami, 1999).

Treatment of bacterial vaginosis

Bacterial vaginosis characterized by reduction of native lactobacilli is one of the most prevalent vaginal infections, and antimicrobial therapy is frequently ineffective. ProDURA and placebo were given to 40 Indian women diagnosed with bacterial vaginosis and with symptoms including white discharge, pH greater than 4.7, burning micturition, itching, soreness, and redness at the vulva. Subjects were divided into two groups, with 20 consuming the probiotic and 20 given the control. The probiotic group subjects were assigned to receive a dose of antibiotic therapy ofloxacin – Ornidazole – at the same time as two probiotic capsules (10 billion CFUs of *Bacillus coagulans* Unique IS-2 per capsule) while the control group received only antibiotic therapy. At the end of the treatment, 80% of the probiotic group subjects showed a significant positive response as a reduction of vaginosis symptoms compared with the placebo group, which exhibited reduction in only 45% of subjects. The results indicate that *Bacillus coagulans* Unique IS-2 can provide benefits to women being treated with antibiotics to more successfully treat bacterial vaginosis (Sudha, Yelikar, 2011).

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Bile and acid tolerance

The bile tolerance and resistance to acids of *Bacillus coagulans* were studied in MRS broth subjected to low pH conditions (2, 2.5, and 3) and increasing bile concentrations. *Bacillus coagulans* tolerated bile concentrations over 0.3% (w/v) (Hyronimus, 2000). This ability to survive the harsh conditions of the gastrointestinal environment demonstrates the durability and tolerance of this probiotic.

Safety

In a study of acute and subacute oral toxicity of *Bacillus coagulans* Unique IS-2 (ProDURA), Sprague Dawley rats fed a single dose of 3,250 and 6,500 mg/kg b.w./day (5×10^9 spores/g in water) and chronic doses of 130, 650, and 1,300 mg/kg b.w./day (5×10^9 spores/g) for 14 consecutive days showed no treatment-related changes in clinical signs, bodyweight, food intake, urinalysis, blood chemistry, clinical chemistry, gross pathology, and histopathology at both time intervals. Strain *B. coagulans* Unique IS-2 did not reveal any clinical symptoms up to 1,300 mg/kg b.w. dose (5×10^9 CFU/gram) when administered for 14 days, which was considered "No Observed Adverse Effect Level." The results demonstrate that the strain *B. coagulans* Unique IS-2 may be considered as nonpathogenic and safe for human consumption (Ratna, 2011).

References

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