Product Monograph: ***TRANSBIOTIC™***

TRANSFORMATION
THE GENESIS OF GOOD HEALTH®

Transformation's Professional Protocol™ Transbiotic™ was formulated with an innovative prebiotic developed to support the growth of healthy bacteria in the gut through a mechanism that is neither fiber nor starch-based. The unique PreforPro® works synergistically with probiotic strains to combat bacterial diseases such as candida, SIBO, and UTI's. This formula is great for eliminating E.coli and other pathogen transmission from food and water, making it ideal for travelers and those immune to antibiotics. This product is also unique with the introduction of bacillus subtilis, an endospore-forming bacteria which can withstand extreme temperatures and environments. The hardiness of the bacillus subtilis attributes to a longer shelf life, no need for refrigeration, and lower CFU count to reach maximum effectiveness.

The growth of microorganisms and infectious diseases continues despite the fact that our use of prescriptive and over-the-counter antibiotics, antifungals, antivirals, antiseptic soaps, and cleaning disinfectants has dramatically increased over the past few decades. The World Health Organization estimates that by 2050, antibiotic-resistant bacteria will cause upwards of 10 million deaths a year around the world. The emergence of pathogenic bacteria with resistance to multiple antibiotics has reduced the effectiveness of antibiotic treatment of infections. As cases of infection caused by antibiotic-resistant bacteria increase, there is growing concern over the use of antibiotics in both human and animal medicine. The impending ban of antibiotics in animal feed, the current concern over the spread of antibiotic resistance genes, the failure to identify new antibiotics, and the inherent problems with developing new vaccines make a compelling case for developing alternative prophylactics.

This resistance to antibiotics amongst bacteria should come as no surprise since it is well documented that with time a microorganism will learn to adapt to any threat to its survival. These species not only adapt, but they pass their new resistant traits onto other species of bacteria rendering antibiotics useless against them as well. An inability to control pathogenic bacteria creates an imbalance in the microbiome, creating a great threat to our immunity and ability to fight disease. The specific effects of a broken microbiome can be poor nutrient absorption and digestion as well as poor mental, metabolic, and immune function. Everything from our energy levels to our mood, mental state, and weight stems from the balance of good flora inside the GI tract.

The digestive tract contains trillions of microorganisms that constantly compete for space and nutrients. It is also highly susceptible to attacks from bacteria, which can result in a weakened immune system. Therefore, it is important for beneficial bacteria to outcompete harmful bacteria in order to maintain a proper balance of intestinal microflora and overall good health. Probiotics provide a solution to this problem since they are the sworn enemies of pathogenic bacteria, fighting them off one by one to protect our health and longevity. Our body's probiotics comprise 70% of our immune response. Probiotics work with the body's immune system to stimulate an array of antibodies and immune cells that identify and break down infectious microbes. To illustrate the immune effects of probiotics, one might consider the increasing emergence of foodborne Escherichia coli (*E.coli*) outbreaks. Our bodies typically already contain *E.coli* and Salmonella within the intestinal tract. However, we do not always get sick due to healthy bacterium such as the *Lactobacillus* and *Bifidus* species keeping the unwanted population under control. Should new pathogenic colonies arrive, these probiotics will mobilize natural antibiotics to limit the invasion.

Failure to continuously replenish the body with good bacteria can weaken the natural antibiotic response allowing certain aggressive strains of *E. coli* bacteria to outgrow and consume more resources than beneficial bacteria. This results in an imbalance of intestinal microflora and small intestinal bacterial overgrowth, which is associated with many conditions. *E.coli* is one of the most frequent causes of many common bacterial infections, including cholecystitis, bacteremia, cholangitis, urinary tract infection (UTI), and traveler's

diarrhea as well as other clinical infections such as neonatal meningitis and pneumonia.

Among the large number of probiotic products in use today are bacterial spore formers, mostly of the genus Bacillus. Used primarily in their spore form, these products have been shown to prevent gastrointestinal disorders, and the diversity of species used and their applications are astonishing. The durability of soil-spore probiotics also allows for lower CFU counts due to their ability to survive various temperatures and environments. Their ability to stand up to extreme conditions is what keeps them alive for millions of years. In fact, they can be stored at any temperature without any deleterious effects.

Prebiotics help beneficial bacteria, known as probiotics, grow faster than harmful bacteria. More specifically, prebiotics are defined as natural sources of nutrients that benefit the host by stimulating the growth and activity of good bacteria in the digestive tract, thereby improving the health of the host. While their benefit is well known, most prebiotics used are fiber or starch-based and can have some drawbacks. Common concerns related to prebiotics include: large amounts are required to show effectiveness; complaints of gas, bloat, and discomfort; and environmental sensitivity. Since fiber or starch-based prebiotics can limit tolerance of a probiotic in some individuals, alternatives in the form of bacteriophages for prebiotic benefit can be used. Highly specific bacteriophages may be classified as prebiotics since they enhance the growth of beneficial bacteria in the gastrointestinal tract. Beneficial GI bacteria such as bifidobacteria, lactobacillus, and others are in a constant battle for food and space. Inhibition of the growth of neutral or potentially harmful bacteria creates an availability of space and resources to allow the growth of beneficial organisms.

Bacteriophages, or simply phages – whose name means to eat or devour in Greek – are benevolent viruses that exclusively infect bacteria. Phages are the most abundant naturally occurring organisms on earth and are relatively benign. We are surrounded by phages, as they can be found virtually everywhere, including in soil, food, and drinking water. They prey on bacteria, and bacteria cannot become resistant to them. Recently, strictly lytic bacteriophages were isolated for human consumption and have been shown to act as prebiotics when consumed. These phages are related to the virulent phages T4 and T1 and specifically target harmful strains of *E. coli* bacteria in the digestive tract. They support the growth of beneficial bacteria in the digestive system by decreasing harmful strains of *E. coli* from growing and consuming essential nutrients. The lysis and subsequent destruction of *E. coli* bacteria provides the needed space and nutrients for beneficial bacteria to thrive in the digestive tract and prevents bacterial infections by maintaining the proper balance of intestinal microflora in both the small and large intestines.

Safety of Soil-Based Spore Formers

Among the soil-based spore formers, *bacillus coagulans* and *bacillus subtilis* have undergone the most clinical human research. There are more than one hundred species of bacillus bacterium, and because some of them can be harmful, it is important to know exactly which species and strains are contained in any probiotic formula you are using. Experts at the FDA consider *bacillus subtilis* safe and have included it on the list of GRAS (Generally Recognized as Safe) food supplements. They found this helpful bacteria is a natural part of a healthy gut environment. Minimal amounts of spore-based organisms are needed to control putrefaction in the intestinal mucosa. *Bacillus subtilis*, for example, was used for centuries by Arabs for dysentery. Soil-based spore formers have also been observed breaking down hydrocarbons and other molecules, allowing better absorption of difficult-to-digest foods. Another benefit is their ability to aggressively attack and ingest other pathogens such as *Candida*, *Penicillium frequens* and *notatum*, and *Aspergillus niger*. *Bacillus subtilis* can serve as a cooperative probiotic and is shown to be more aggressive than probiotic lactobacilli and bifidobacteria species.

Safety of Bacteriophages

Bacteriophages (phages) are viruses that infect and replicate within bacteria. As demonstrated in *Figure 1* below, the phages use their pointed tails to inject their DNA into the bacterial host cell. By attaching to the cell membrane and injecting their DNA, the phages are able to utilize the genetic replication machinery of the bacterial host cell to make copies of themselves. The new phage progeny then lyse the cell wall, which bursts open to release the phage and the cell contents into the environment. The multiplied phage population then seeks out more host cells and continues to reduce the host population. This process makes space available for the probiotics, which can utilize the nutrients to increase their population.

The use of virulent bacteriophages for the treatment of bacterial infections started in the early 1920's but was abandoned in the 1940's with the introduction of antibiotics, due to a failure to properly understand the

complex nature of phages and their specific bacterial targets. Western nations are becoming more aware of the possibilities of phage treatment for antibiotic-resistant bacteria. Phages are considered self-amplifying and self-limiting. They are able to replicate and maintain high concentrations of particles as long as susceptible bacteria are present. In the absence of host bacterial cells, their activity ceases, and they are flushed from the body.

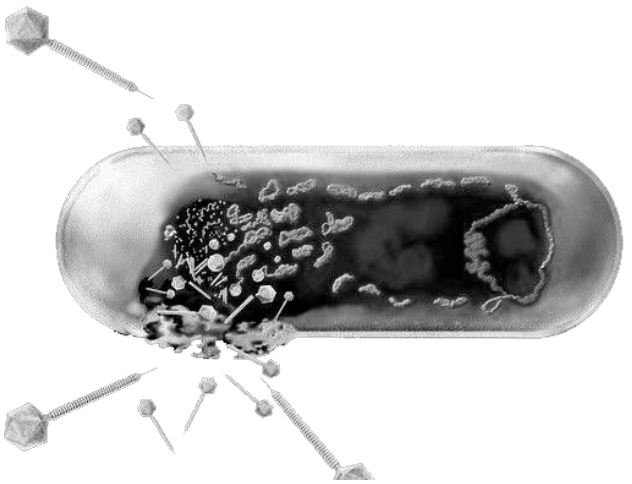

Fig 1. example of the PreforPro® prebiotic bacteriophage

Phage therapy has distinct advantages over antibiotics because the use of "wild type" phage with a multitude of different types of phages is too variable for bacterial resistance to form. Additionally, the phages keep intact healthy microflora and maintain a good microorganism count by preventing against small intestinal bacterial overgrowth (SIBO). The abundance of phages in the environment and the constant exposure of mammalian species to them support a natural tolerance for phages and reflect their general safety. Research involving both animal and human consumption studies has also shown that humans are exposed to large numbers of phages daily through food and water without evidence of harmful effects. No allergic reactions in humans have been reported despite evidence that phages enter circulation.

FORMULA RATIONALE

Lactobacillus acidophilus has as its main function digestive support, producing key enzymes such as lactase, lipase, and protease. As a result, it supports better nutrient absorption, especially vitamin K and B vitamins, lactose, calcium, and fatty acids. Studies are finding *L. acidophilus* effective for lactose intolerance, colitis, impaired intestinal permeability, dyspepsia, IBS, and diarrhea. It is also supportive to a healthy immune system, reducing inflammation, allergies, and infections such as overgrowth of candida albicans, *H-pylori*, *E. coli*, salmonella, shigella, and staphylococcus. It also produces antibiotic substances such as acidolin, acidophillin, lactobacillin, and lactocidin. *L. acidophilus* also shows benefit for those with cholesterol imbalances.

Lactobacillus casei is naturally found in the mouth and intestines of humans. It is well studied and accepted for its beneficial effects on digestion including reduced diarrhea/constipation, reduced inflammation in IBD, and lactose intolerance. *L. casei* has been reported to also support healthy immunity.

Lactobacillus plantarum is one of the most versatile probiotics and is also considered a "starter" as it promotes the growth of other beneficial bacteria. It is found in plant material and the gastrointestinal tract of animals, including humans. It has been used in the fermentation of foods for hundreds of years, and is a healthier option in food preservation. Along with promoting normal digestive health, *L. plantarum* has been shown to be an effective treatment for irritable bowel syndrome (IBS), Crohn's disease, and colitis. It has the ability to destroy pathogens and to preserve critical nutrients, vitamins, and antioxidants. It has also shown the rare ability to produce *L. lysine*, a beneficial amino acid. In the area of immune support, *L. plantarum* has been shown to reduce risk of infections, inflammation, and is considered to be anti-pathogenic.

Bacillus subtilis is considered an ideal probiotic because of its ability to safely survive the low pH balance in the early GI tract and to thrive once it reaches the intestines. Unlike some probiotics which have proven to be somewhat fragile, *B. subtilis* can form a protective endospore to keep itself alive almost indefinitely. Due to its hardiness, smaller doses are able to achieve therapeutic outcomes. It is important to note that while in the same genus as some disease-causing bacillus species, it is not to be confused with them due to the ability to distinguish between the helpful and harmful strains. *Bacillus subtilis* stimulates the immune system to a considerable extent, causing it to produce a broad spectrum of antibodies, including those which fight gut and urinary tract diseases, Rotavirus, Shigella, and food borne illness.

PreforPro® – the Prebiotic Difference

Prebiotics are generally fibers or starches that help support healthy bacteria in the gut. Transformation's Transbiotic™ contains PreforPro®, a prebiotic that

supports the growth of healthy bacteria in the gut through a mechanism that is neither fiber nor starch based, but rather bacteriophage based. The use of bacteriophages in place of fructo-oligosaccharides allows for a more tolerable probiotic with greater effectiveness. PreforPro® addresses the drawbacks of typical prebiotics on the market. Benefits include:

- effectiveness in small doses within hours
- ability to function in both the small and large intestine
- does not cause bloat, gas, or discomfort
- not affected by varying gut environments
- works in a broad spectrum of probiotic species

The PreforPro® prebiotic also helps to extend the shelf life to 18 months.

Inactive Ingredients

This product is encapsulated in a delayed release capsule containing hypromellose, pectin, and water.

DRcaps® Delayed Release Capsules by Capsugel provide better delivery of nutritional ingredients that are acid sensitive. DRcaps® are the alternative to enteric coating which may utilize plasticizers, additives, chemicals, and/or solvents. DRcaps® are made with an innovative hypromellose (HPMC) formulation. These capsules are Vegetarian society certified, Kosher certified, and vegan approved.

COMPONENT BENEFITS

Transbiotic™ was formulated with an innovative prebiotic developed to support the growth of healthy bacteria in the gut through a mechanism that is neither fiber nor starch based.

Each capsule is formulated to include:

TZyme® Probiotic Blend (1 billion cfu) 299 mg

Lactobacillus acidophilus
Bacillus subtilis DE111®
Lactobacillus casei
Lactobacillus plantarum

PreforPro® 15 mg

LH01 - Myoviridae
LL5 - Siphoviridae
T4D - Myoviridae
LL12 - Myoviridae

Other Ingredients:

Hypromellose
Pectin
Water

SUMMARY

It is not surprising that the native microbiota have been found to play an important role in human health. Most of these bacteria are not harmful, and in fact contribute positively to human health, growth, and development. Due to diet, lifestyle, environment, and certain medications, the balance of good and bad can be altered, creating a potentially harmful situation. It is important that the balance of microbes be maintained to favor the beneficial bacteria over the pathogenic ones. Based on over thirty years of clinical experience and the current research findings, one of the most effective ways to support GI health is through regular probiotic supplementation.

CLINICAL APPLICATIONS

Possible indications for Transbiotic™ include:

- Prevention and wellness
- Digestive disorders
- Constipation
- Diarrhea
- Inflammatory bowel disorders
- Gas and bloating
- Dysbiosis
- Frequent antibiotic use
- Weakened immunity
- Lactose Intolerance
- Viral / bacterial infections
- Yeast infections
- Frequent travelers
- Food borne illness

RECOMMENDED USAGE

Take one capsule upon rising or at bedtime with at least 8 oz. of water or as directed by a healthcare practitioner.

PRODUCT SPECIFICATIONS

Transbiotic™ is available in bottles of 30 capsules. Refrigeration is not required but recommended for optimum activity.

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