

# FAQs

## Frequently Asked Questions about MegaSporeBiotic

*Including from our webinar: "Forget what you know about probiotics: The latest research on nature's true probiotics"*

### **Q: What is MegaSporeBiotic?**

A: MegaSporeBiotic is the first, All Spore, pharmaceutical grade probiotic product that takes advantage of nature's design for a perfect and true probiotic. Physicians Exclusive has identified key spores as both safe and effective at supporting digestive health and boosting immunity. Physicians Exclusive is making these spores available for the first time in the dietary supplement industry. MegaSporeBiotic is the first dietary supplement probiotic that contains 5 proven pharmaceutical grade bacillus spores including the patented carotenoid rich probiotic strain – B. indicus HU36.

### **Q: Why is MegaSporeBiotic different from other probiotics already on the market?**

A: MegaSporeBiotic is the only product with 5 pharmaceutical grade bacillus spore strains. In addition, MegaSporeBiotic is the first probiotic to introduce a strain that produces key nutrients in the digestive system. In this case, the nutrients produced are powerful carotenoid antioxidants. Carotenoids are the beneficial antioxidants found in colored fruits and vegetables. Carotenoids from dietary supplements however are poorly absorbed and most people do not eat as many colored fruits and vegetables as they should, thus supplementation with a carotenoid rich probiotic is highly important. These beneficial bacteria produce high levels of carotenoids right at the sight of absorption, thus allowing for optimum uptake into the body. MegaSporeBiotic is the first and only probiotic with such a feature.

### **Q: What is a probiotic?**

A: Probiotics are the fastest growing category in the supplement industry. Recent research done by the NIH has defined probiotics by a strict criteria:

1. The organism must be a normally occurring organism in the digestive tract.
2. In order to consistently trigger a healthy boost in immune function the organism must be supplemented in concentrations higher than what normally occurs in the digestive tract.
3. The organism must be able to survive in the digestive tract as well as in the environment.

Interestingly enough there are almost no probiotics in the marketplace that meet all three of these criteria!

### **Q: Why doesn't MegaSporeBiotic contain lactobacillus or bifidobacter species of probiotic?**

Lactobacillus and Bifidobacter species do meet the first requirement according to the new probiotic criteria defined by research from the Human Microbiome Project that is run by the National Institutes for Health. That is they do naturally occur in the digestive tract. In fact lactobacillus and bifidobacter species are in very high concentrations in the digestive tract of humans. This is exactly why these 2 bacteria cannot meet criteria two. There are in excess of 20 trillion lactobacillus and bifidobacter species in the average human digestive tract. Supplements today contain 100 billion strains on the high end. This is nowhere near the amount that would be necessary to stimulate the immune system. This also assumes that the bacteria will survive the digestive tract. Research shows that a majority of orally supplemented lactobacillus and bifidobacter species are destroyed by the conditions found in the stomach and upper digestive tract. Lastly, most lactobacillus and bifidobacter species are anaerobic organisms that are designed to live in the digestive tract. They don't normally live in the environment because they are sensitive to the presence of oxygen, UV light and other chemicals found in the natural environment. This means they do not fit criteria 3 of our new definition of probiotics. Its important to note that an individual gets their initial dose of lactobacillus and bifidobacter species from their mother through birth and breast feeding. Later in life, orally derived

probiotics must be organisms that live naturally in the environment as well at the digestive system so that exposure to these organisms are possible.

**Q: I am currently taking a probiotic and it seems to be working just fine. Why should I switch to MegaSporeBiotic?**

A: MegaSporeBiotic offers functions that other common probiotics do not. Effective probiotics go beyond digestive health. Effective probiotics are critical for immune function, immune stimulation, managing populations of dangerous bacteria, digestion of cholesterol, neutralizing toxins, production of key nutrients, etc. Unless your current probiotic contains high doses of several spore strains, it is not providing all these beneficial affects. Use MegaSporeBiotic to take complete advantage of all the functions of a true probiotic.

**Q: What spores are present in MegaSporeBiotic?**

A: MegaSporeBiotic contains 5 pharmaceutical grade strains that each have unique function and thus contribute to the overall effectiveness of the product. Below is a brief description of each:

1) Bacillus Indicus HU36 – The first carotenoid rich probiotic strain offered to the dietary supplement market. An isolate from humans, Indicus HU36 produces high levels of powerful carotenoids (antioxidants) at the site of absorption. Carotenoids do not survive the gastric system well. HU36 however, has demonstrated the ability to survive past the stomach acid and produce the carotenoids at their site of absorption in the gut. This makes the carotenoids produced by HU 36 the most bioavailable supplementary carotenoids in the marketplace. HU36 gives MegaSporeBiotic a function that no other probiotic formulations on the market can claim-it provides key nutrients in their most potent form.

2) Bacillus Clausii – This strain is the largest selling strain of prescription probiotic in the world. For the first time, this strain is made available to the U.S. dietary supplement industry and is available exclusively to healthcare professionals. Bacillus Clausii is recommended for use during antibiotic treatment due to its ability to resist damage from a variety of common antibiotics. MegaSporeBiotic has the unique function of being a powerful supplement that can be used in adjunct with antibiotic therapy to keep the organisms balanced in the gut.

3) Bacillus Subtilis HU58 – Bacillus Subtilis has been extensively studied on a genetic and functional level. There are several probiotic products in the pharmaceutical and agricultural markets that utilize this powerful probiotic. One very interesting function of Bacillus Subtilis is its ability to produce nearly 12 strong antibiotics that are potent fighters of opportunistic and harmful bacteria. Bacillus Subtilis HU58 offers MegaSporeBiotic the ability to prevent harmful bacteria growth in a variety of conditions. In addition, HU58 produces a very healthy compound called Nattokinase. Nattokinase is secreted from vegetative cells of Bacillus subtilis and has been shown to reduce blood pressure, reduce cholesterol and reduce excessive clotting by fibrinolysis. Along with Nattokinase, Bacillus subtilis also produces a number of other nutrients that have systemic health benefits such as B vitamins and Vitamin K2. Bacillus subtilis HU58 offers MegaSporeBiotic the important function of fighting off pathogenic bacteria and producing key nutrients in the gut itself. In addition, HU58 is an extremely potent immune stimulator. It has the function of germinating in the small intestines to some degree and this offers the effect of broad-spectrum immune stimulation.

4) Bacillus Licheniformis – A probiotic often found with Bacillus subtilis and other bacillus species, licheniformis has been shown to have a potent effect of preventing the growth of harmful bacteria via the production of a common antibiotic called bacitracin. It is also a potent immune stimulator. Another very important feature of bacillus licheniformis is its ability to produce highly effective and stable protease enzymes in the gut that assist in the digestion and absorption of proteins. Lastly, licheniformis also produces the whole spectrum of B vitamins in the gut including folic acid and biotin and acts as an important nutrient factory in the digestive system.

5) Bacillus Coagulans – A very well studied probiotic in the spore family that has a profound effect on inflammatory conditions such as IBS and Crohn's. Bacillus coagulans offers MegaSporebiotic an expanded effect of controlling these common inflammatory bowel conditions in addition to its potent immune boosting activity. Coagulans has the unique attribute of producing lactic acid and specifically the L+ optical isomer of lactic acid, which has been shown to have a more profound effect on immune stimulation and gut defense than the other forms of lactic acid produced by

conventional probiotics. Coagulans is also a tremendous colonizer and thus assures proper colonization of MEGAsporebiotic, which in turn will produce the beneficial effects required. Coagulans also plays a key role in digestion of food and absorption of nutrients. In fact, Coagulans can digest incoming fat to reduce the uptake of cholesterol. Coagulans adds another dimension to MEGAsporebiotic, giving it a potent ability to fight inflammatory conditions, aid in digestion and prevent the growth of harmful bacteria.

**Q: What is the shelf life of MegaSporeBiotic?**

A: 2 Years, expiration date will be indicated on the box.

**Q: Why do some capsules contain black flecks or yellow coloring?**

A: The strains in MegaSporeBiotic can range in color from White/Yellow in appearance to Black/Gray-ish in color. When mixed together, capsules can contain black flecks or a yellow hue. MegaSporeBiotic is a pure fermentation extract and with nature there is no color uniformity. It is completely natural and color variation is quite common from batch to batch. Our product is routinely tested a minimum of four (4) times before it reaches the end consumer. MegaSporeBiotic is a pure fermentation extract and with nature there is no color uniformity.

**Q: What are the side effects of taking a probiotic/MegaSporeBiotic?**

A: None have been reported for MegaSporeBiotic. However, some individuals can experience some digestive discomfort initially due to changes in gut bacteria. Individuals with SIBO, Candida, and major digestive issues are highly advised to consult with a health practitioner for education on proper dose protocol. This may include starting at a 1/4- 1/2 capsule dose every other day and slowly titrating up to a full dose of 2 capsules over a long period of time.

**Q: Where can I purchase MegaSporeBiotic?**

A: Through your health care professional. If your health care practitioner does not carry MegaSporeBiotic, ask them to call 855-729-5090 for a supply.

**Q: Any significance of taking after a meal? What about if on an empty stomach?**

Yes. The amino acids and carbohydrates in food help the spores move from their dormant (spore state) to their active (vegetative state) form in the GI. There are tremendous immune benefits if the spores are made to germinate into their vegetative state in the upper GI itself and so taking just after a meal (10-20 mins after) is ideal.

**Q: If a probiotic has no spot to colonize, can it cause problems until it is expelled?**

In theory, yes. The bacteria could be seen as an invading species and the body can mount an immune response to it. The response would be a pro-inflammatory innate response which can then harm other tissues in the area as well. It's important to know that a supplemented probiotic has a place in the individuals microbiota – with bacillus spores being such universal probiotics, you can feel comfortable that they have a spot to colonize every time.

**Q: How do you know what to give patients and for what conditions?**

Health in general starts in the gut. Hippocrates said it in 400 B.C. and since then modern science has proven it. Any immune dysfunction (auto-immune, allergies, food sensitivities, rashes, psoriasis, eczema, rheumatoid arthritis, gout, etc.) can be traced back to a dysfunction in the GI. Any inflammatory condition can as well. Now, modern science has shown us that weight control, mood, depression and other mental disorders are also connected to the gut (the second brain). Even chronic diseases such as diabetes, heart disease, cancer, etc. can be traced back to the gut. Everything starts in the GI. With that in mind, all your patients should be on a daily dose of this probiotic as well as a diet that supports a healthy flora. It's as essential as any multivitamin, greens drink or fish oil product that people may use as part of their daily nutrition. So start all patients on it and nearly everyone (despite their condition or ailment), will see some benefit as you are now replacing an essential nutrient that has been missing from their diet.

For patients that present with a strong yeast issue or those with strong inflammatory conditions (Crohn's, IBD, Ulcerative colitis, etc.) should titrate the dose up slowly. Starting with 1 cap every other day for a week or until they can tolerate, then 1 cap per day using the same discretion and finally 2 caps per day. Symptoms to watch out for include intestinal cramping and diarrhea.

**Q: Can live fermented foods colonize the gut effectively? And would these spore probiotics help the SIBO condition, which has been characterized as an overgrowth of good bacteria. Also can candida excess yeast be helped?**

Fermented foods are great for the GI, but the benefits don't typically come from the microorganisms in the food going in and colonizing, it comes from the ferment itself. The many nutrients the bacteria made while fermenting the foods are what helps the GI and the immune system from fermented foods. The problem however is they don't do much to alter the Dysbiosis one may have in the GI. This is where a true and effective probiotic comes in.

MegaSporeBiotic contains one of the only strains that have been shown in studies to actually alter the GI flora when it colonizes. This is a difficult task when you consider that the flora is made up of nearly 100 trillion cells and the probiotic is there in a concentration of just a few billion. But some strains are specialized to do this type of work and our strain bacillus Subtilis HU58 is one such strain.

Another key strain in the formula (bacillus clausii), has been used as a prescription treatment for SIBO for a number of years. It can be very effective in your patients suffering with SIBO.

We have had numerous cases of candidiasis that have seen great benefit from this product. There can be some strange looking excrement for a period of time as the yeast leaves the system, but we have always seen very consistent and positive results.

**Q: So, Greek yogurt does not work? Where do you get the good products for your patients?**

Unfortunately yogurts and yogurt based drinks (including Kefirs) don't work as probiotics in our experience and research. There are some benefits from the fermentation process and those benefits are contained in the product in the form of micro-nutrients. But those strains used in yogurts and other fermented dairy products, do not have the ability to survive the harsh stomach and colonize in the GI. For a true probiotic, we only work with MegaSporeBiotic.

**Q: In the case of dysbiosis would there be a need to reduce the population of the good guys and bad guys before repopulating the GIT?**

Yes, you can certainly have too many of certain good guys. In fact, a commensal bacterium in your GI is a "good guy" only until a certain point. Once that "good guy" reaches a certain population level, it can easily become a "bad guy" as in being a problem for the system. This is the issue in SIBO. One of the most profound effects of these bacillus spores in MegaSporeBiotic is their ability to "police" the GI. They facilitate and support the growth of the "good guys" that are under population and can reduce the numbers of the bacterium that are over-grown. They create a modulating effect on the microbiota. Start with MegaSporeBiotic, let these strains regulate the microbiota, then use foods and supplements that support the growth of the good bacteria. Taking the spores daily will ensure that the balance is not lost again.

**Q: How is your product different from Lactobacillus sporogenes by thorne?**

Lactobacillus Sporogenes is a mislabeling of Bacillus Coagulans. We will refer to the product under its correct name which is bacillus coagulans. Bacillus coagulans is a spore former with the benefits we talked about with our product, in fact, we also have bacillus coagulans in our formulation as one of the 5 strains. There are however some very important differences between MegaSporeBiotic and the Bacillus Coagulans product from Throne, they are as follows:

- 1) We are verified to be in 100% spore form – this is critical as spore formers are also unable to survive the journey to the intestines unless they are in spore form. From what we have seen, other products that may contain 1 or 2 spores have only some of those strains in spore form; the rest is in vegetative cell form. This makes them less effective.

- 2) We have 5 critical strains that work in synergy. These bacillus spores aren't found by themselves in nature. In nature these spores are typically in co-existence with other bacillus spores and they support one another in the human body. Having an effective consortium of the right spores is more how nature intended. In addition, these various spores perform different functions in the body. Having just 1 of the strains means at least 1/5 less function.
- 3) With 5 strains you get a whole spectrum of nutrient production that you won't see with just 1 strain. Between the 5 they produce the whole spectrum of B vitamins, quinols, vitamin K2, digestive enzymes, etc. Each of the strains produces a different set of micronutrients.
- 4) Lastly, ours contains the patented bacillus indicus HU36 – this is the world's first carotenoid (antioxidant) rich probiotic. This strain colonizes in the GI and produces RDA levels of carotenoids right at the site of absorption.

**Q: Can probiotics or spore probiotics be safely taken when breast feeding or pregnant?**

Yes, we have a number of patients and individuals who are taking the product during pregnancy and nursing. If the pregnant or nursing mother has strong inflammatory conditions or yeast issues, they should also be titrated up so there isn't a detox reaction.

**Q: When using MegaSporeBiotic, is dosing once per day or more often depending upon clinical presentation of the patient?**

The product should always be dosed once per day only. There is no need or benefit in splitting the dose to 2 or more per day or doubling the dose of 2 capsules. You want to get the full dose of probiotics in at once. This again is best about 10-20 minutes after a meal.

**Q: What test do you recommend for stool – flora evaluation?**

Comprehensive Digestive Stool analysis is the best way to evaluate the composition of Flora in the bowel.

**Q: Would like to know your view on vsl#3 and Saccharomces Boulardii? And the use of Lactoferrin?**

VSL 3 is a probiotic formulation that uses the same rationale as 95% of probiotics out in the market place. It uses 8-10 strains of various lactobacillus and bifidobacterium species but has focused on formulating the largest numbers of these strains – in one of their formulations they claim nearly 900 Billion CFU. In our opinion, it is an enhanced version of many probiotics found in the market today. It may have some effect on acute symptoms, but we would not feel comfortable saying that it performs as a "probiotic" per the World Health Organization definition.

*Saccharomyces boulardii* is a strain we like and we believe is effective. In fact, we have used it ourselves. It fits nature's design as a probiotic and the scientific definition as well. It is however a probiotic fungus and not a bacteria. Although it can be effective against diarrhea, it has limited function. To use it by itself as a daily probiotic is incomplete therapy. We use MegaSporeBiotic and supplement from time to time with *S. boulardii* in cases of severe and acute diarrhea.

Lactoferrin is an immune component that can be useful for acute infections or conditions. It's not designed to be used chronically. If you look in nature, the highest concentration of lactoferrin is found in human colostrum, then the concentration reduces in human milk. Colostrum only comes in the first few days after birth and then milk comes in where nature has designed for the lactoferrin concentration to reduce. Of course the milk eventually stops as well and so humans have not evolved to require or use lactoferrin their entire life. It's important to establish the innate immune system in newborns and to protect the newborn from infection as newborns are not producing their own immune cells and then it becomes less important as the newborn matures and starts to produce its own innate immunity components. The strains in MegaSporeBiotic are a potent immune modulator and they do this equally for children and adults. In fact, it has been shown that our immune systems are likely designed with a need for this daily stimulation and modulation by bacillus spores. This would not be surprising from an evolutionary stand point when you consider that our ancestors got a daily dose of these strains their entire lives.

**Q: What is the general length of time needed to get the gut to self-inoculate? I.e. how long do you have to take these spores before you can ease up and survive on your own?**

Nature has designed these spores to be a daily, foundational food. They are transient microorganisms, thus they don't stay in the GI forever. They go in, perform a function and leave. This is important as this helps keep their numbers in the GI relatively low which means each dose has an effect. It takes them about 21 days to reach a steady state concentration in the GI with daily supplementing and at this stage is where they are the most effective in regulating the GI. At this time, it's important to consume a diet low in refined sugars and higher in fibers to facilitate the growth of the individual's own good bacteria. In fact, the spores can also increase the growth of the good bacteria. Between the spores being present and the improved diet, the individual will go into a state where they have the right microbiota balance. If the spores are removed, then you are tipping the balance back towards Dysbiosis. The use of the spores on a daily basis is a very important maintenance practice. We are bombarding our GI on a daily basis with things that shift the balance to Dysbiosis and so the spores are required to remain and police our GI.

**Q: What are the actual number results from GI study of all the carotenoids, vit K2, etc.?**

In the GI study we focused on the carotenoids in terms of being able to enumerate the quantities produced and absorbed. We did not focus on the vitamins and enzymes. The study showed that on average, after 3-4 weeks of daily use, the strain was producing roughly 800ug of carotenoids per day. These carotenoids are produced right at the site of absorption and are thus roughly 10 times more bioavailable than standard, supplemented carotenoids. The researchers concluded that it reaches the Recommended Daily Allowance of carotenoids.

**Q: Are you working on a spore type product for fecal transplanting?**

No, it's not necessary to administer spores in that manner. There are 2 main reasons why fecal transplants can be effective; 1) you can administer a high enough dose of the lactobacillus and bifidobacterium species and 2) you are not passing through the harsh gastric barrier, thus they can survive to reach the intestines.

Spores can already survive the harsh gastric barrier and can be supplemented in effective dosages per oral dosing, thus they don't need to be administered through the rectum.

**Q: Any healing crisis that may develop when you first start these and they start killing off yeasts or other pathogens?**

As with any product that is effective in restoring balance to an unhealthy intestinal tract the chance for your patients to experience herxheimer reactions is possible. Because of this we recommend that the dose be titrated up slowly to control detox reactions. The most frequent symptoms reported are intestinal cramping and loose stools. Decreasing dose eliminates any uncomfortable symptoms.

**Q: What Conditions are specific for MegaSporeBiotic?**

Clinically, we have benefitted the following conditions and other doctors have reported major benefits in these listed conditions as well:

- Crohn's, IBS, IBD and colitis
- Minor and major gastro discomfort – gas, bloating, indigestion
- Acid reflux/GERD
- Hashimoto's disease
- Cystic acne
- Rheumatoid arthritis
- Allergies, asthma, eczema, psoriasis.

**Q: Can pets (cats & dogs) be supplemented with MegaSporeBiotic?**

Yes, the strains are universal probiotics and are used in all types of animals and livestock throughout the world, including marine life. Take one capsule, pull it apart and sprinkle it on their food.

**Q: Will the spores still work if you pull the pill apart and still take it?**

Absolutely. This is the preferred way to administer to children. It can be pulled apart and the powder mixed into nearly any food or drink. It is temperature stable, so it can even be mixed into hot tea, coffee or soup. There is no real taste impact of the powder.