Efficacy of N-SORB, a Proprietary KD120 MEC Metabolically Activated Enzyme Formulation: A Randomized, Double-Blind, Placebo-Controlled Investigation and Case Studies

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Keywords: N-SORB; Digestive enzyme; Clinical Study; DEXA; Pittsburgh Sleep Quality Index (PSQI); Quality of Life; Safety; Independent Case Studies

ABSTRACT

Background: Every biochemical transaction in the body utilizes enzymes. Insufficient enzyme availability leads to impaired digestive health, which tolls approximately 200 million sick days, 50 million visits to physicians, 16.9 million days lost from school, 10 million hospitalizations, and a total of 200,000 deaths per year. Chronic digestive problems can progress to stomach ulcers, inflammatory bowel diseases and colorectal cancer. Digestive enzymes play an intricate role in vital bio-metabolic functions including disintegration, dissolution, absorption, and metabolism of ingested foods to obtain essential nutrients, including amino and fatty acids, cholesterol, carbohydrates, vitamins, and micronutrients for the growth, metabolism, antioxidant protection, and immune-boosting benefits to the body. Moreover, proper digestive enzymes significantly improve gastro-intestinal integrity, immunity, cellular functionality and overall health. An ageing population is at increased risk for suboptimal enzyme availability and are more prone to experiencing indigestion, gas, bloating, disrupted gut health, and malnutrition. Disrupted digestive system can impair and exhaust metabolic capabilities and immune health. Sedentary lifestyle, improper nutrition and advanced age-induced decline in digestive enzymes are the major causes of microbiome imbalances, incomplete digestion, and induction of several degenerative diseases and dysfunctions. Moreover, enzyme availability is a rate-limiting factor, not just for digestion, but to a host of systemic metabolic activities. A state-of-the-art KD120 Prodosomed multienzyme complex (MEC) was engineered consisting of natural protease, amylase, lipases, alpha-galactosidase, and glucoamylase from natural sources, and encapsulated in a SK713 SLP (non-GMO soy lecithin phospholipid) Prodosome® absorption technology, which enables rapid absorption beginning in the sublingual mucosa, reduces degradation in the stomach, and then facilitates absorption through the intestinal mucosa starting in the duodenum. The formulation is activated in a pH ranging from 6.0 to 8.5, in contrast to other enzyme formulations, and is directed to be taken in an empty stomach. The Prodosome® technology facilitates rapid absorption and bioavailability of these encapsulated natural enzymes. Earlier clinical studies exhibited that intervention with N-SORB improves sleep, gastrointestinal functions and neuroendocrine benefits.

Objective: A randomized, double-blind placebo-controlled study was conducted to determine the safety and efficacy of N-SORB KD120 MEC in healthy male and female volunteers on several important hematological parameters, digestive and immune health, physical well-

being, and quality of life over a 90-day intervention. Furthermore, eleven physician's supervised case studies in male and female subjects, ranging from 20 and 71 years old with comprised digestion, immune and metabolic maladies, were performed.

Methods: A total of forty-six healthy volunteers (male = 25; female = 21; age: 25.8 12.1 years) were randomly assigned to receive either N-SORB (1 mL, twice daily), prepared in a Good Manufacturing Practices (cGMP)-NSF certified facility, or placebo over a period of 90 consecutive days. All subjects were instructed to possess an honest healthy lifestyle during this clinical investigation. A total of 40 subjects completed the study. Body weight, BMI, lean mass, fat mass, bone mineral mass and total blood chemistry were assessed. Complete blood count, as well as blood glucose, liver enzymes, and lipid profile were assessed pre- and post-intervention. Serum cytokine levels were determined by using a Bio-Plex Pro Human Cytokine 8-plex assay and ELISA. Whole body composition analysis was performed by dual-energy X-Ray absorptiometry (DEXA) to work out body fat mass, lean mass and android and gynoid fat. Body weight, vital sign , and physical health were assessed. Changes in quality of life were examined using the World Health Organization Quality of Life- abbreviated version (WHOQOL-BREF) and sleep quality was assessed using the 24-item Pittsburgh Sleep Quality Index (PSQI) questionnaire. Adverse events were monitored before, during and after completion of the study.

Case studies were conducted in 11 subjects and all necessary permissions were obtained. Physician's (Dr. S. Schutz) supervised case studies were conducted in 4 female and 2 male subjects (age = 69-; 20+-, 30+- and 30+ years, respectively), suffering from digestive problems, who consumed N-SORB (1-1ml packet BID on an empty stomach with the last packet immediately before bedtime) over a period of 3 months in 3 subjects and 1 month in the 4th subject, respectively. While in the second set, two male subjects (age = 71- and 40+ years), suffering from impaired digestion, consumed N-SORB (1-1ml packet BID with the last packet consumed prior to bedtime) over a period of 7 days to 3 months in two subjects, respectively.

In another independent case study conducted under physician supervision at the Center for Bioindividualized Medicine, one male (age = 60), suffering from chronic fatigue syndrome, chronic musculoskeletal pain and digestion; and four female subjects (age = 43-, 46-, 51-, and 56 years, respectively), suffering from fatigue, depression, anxiety, compromised gastrointestinal and digestive functions, leaky gut syndrome, joint pain, obsessive compulsive disorder and hypothyroidism, consumed N-SORB (1-1ml packet BID) over a period of 1-3 months.

Results: A total of 40 subjects successfully completed the clinical investigation. Compared to placebo, changes in blood cell counts including hematocrit, hemoglobin, mean corpuscular volume, platelets and lymphocytes provide evidence indicating consistent trends of improvement. Digestion was significantly improved. Quality of Life (QOL) parameters showed a small but significant improvement in the N-SORB group. A significant increase was observed in AST level in the placebo group at the end of 90 days of treatment, however, no increase was observed in the N-SORB group. No significant changes in BUN, serum creatinine, ALP, ALT, and lipid profile were observed between the placebo and treatment groups before and following 90-day intervention.

In both the case studies conducted independently by the physician(s), respectively. Significant improvement in gastrointestinal and digestive functions were observed, along

with other systemic improvements.

No adverse events were reported in the clinical investigation and case studies.

Conclusion: This clinical investigation demonstrates that 90-day intervention with N-SORB demonstrated significant improvement in digestion, immunity, sleep quality and other health parameters. Improvements were observed in RBC, QOL and PSQI in the N-SORB young health volunteers; and didn't significantly alter cardiometabolic parameters, lipid profile or body composition.

Case studies in eleven subjects significantly improved both digestive and immune health along with other systemic improvements.

Overall, N-SORB boosts digestive health, immunity, sleep quality and overall metabolic health.

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