

Bened Life

Neuralli™ and Neurological Conditions

Neuralli is a medical probiotic providing 60 billion colony forming units (CFU) per dose of the neurologically active probiotic strain *L. plantarum* PS128™. PS128 utilizes the gut-brain axis to provide clinically measurable benefits in neurological conditions such as autism spectrum disorder (ASD). Proposed mechanisms include balancing levels of neurotransmitters such as serotonin and dopamine.

Below are the questions we are asked most frequently about the unique neurological characteristics of the PS128 probiotic strain in Neuralli, clinical evidence for the benefit of PS128 in people with neurological conditions, and how to use Neuralli.



TOP HEALTH CARE PROVIDER QUESTIONS ANSWERED

Q. WHAT PROBIOTIC AND PREBIOTIC INGREDIENTS ARE IN NEURALLI?

A. Neuralli is a combination of a live probiotic bacterial strain and a prebiotic carbohydrate. Each two-capsule dose contains 60 billion CFU of the probiotic strain *L. plantarum* PS128. Experimental studies and clinical trials have shown that PS128 is a unique type of probiotic that provides a benefit to the nervous system. Each two-capsule serving of Neuralli also contains 180 mg of inulin (derived from Jerusalem artichoke or chicory root).

Q. IS NEURALLI SAFE TO TAKE?

A. Neuralli is safe for consumption. PS128 and the other ingredients in Neuralli have been affirmed as GRAS (generally recognized as safe), an FDA designation.

Q. IS PS128 DIFFERENT FROM OTHER PROBIOTICS?

A. Probiotics are living microorganisms that provide a health benefit when given in sufficient quantities. Each probiotic strain (a subset of a particular species) is unique and reacts with our body in a way different from others. The activity of certain probiotic strains in the gut can affect the brain via the bloodstream, immune system, and vagus nerve (i.e., the gut-brain axis). Microbes with such beneficial neurological properties are called “psychobiotics”.

L. plantarum PS128 in Neuralli is a unique psychobiotic strain. In preclinical studies PS128 has been shown to help balance serotonin, dopamine, cortisol, and other molecules that affect mood, mind and movement. In an observational “real world” study in ASD, PS128 demonstrated better effects than other probiotics as a group.

TOP HEALTH CARE PROVIDER QUESTIONS ANSWERED

Q. HAVE CLINICAL TRIALS BEEN CONDUCTED WITH PS128 IN PEOPLE WITH NEUROLOGICAL CONDITIONS?

A. Two randomized controlled clinical trials (RCTs) have been conducted with PS128 in autistic children, and additional studies are ongoing. A 4-week RCT showed reductions in anxiety behavior and improvements in attention, social cognition, and opposition/defiance behavior in the PS128 group.¹ A longer term RCT showed greater improvements when used in addition to another intervention.² In a six-month “real-world” study,³ 87% of autistic participants taking PS128 daily showed improvement, including increased shared attention, communication skills and personal autonomy.

In addition, a single-arm pilot study in adults with Parkinson’s disease, a disorder which is caused by depletion of dopamine-producing neurons, suggested possible benefits of PS128. After three months of use, a majority of participants reported significant improvements in motor symptoms, “off” time, and quality of life.⁴

Q. HOW SHOULD MY PATIENTS STORE NEURALLI?

A. Refrigeration of the product is highly recommended to retain the highest potency. For best results, Neuralli should be stored in its own bottle in the refrigerator. Cold temperatures and the desiccant built into the walls of the CSP vial will help Neuralli retain the highest potency through the Best By date. If Neuralli must be stored at room temperature for a short period, we recommend keeping it in a cool, dry place away from direct sunlight.

Q. THE PRODUCT LABEL SAYS NEURALLI IS A “MEDICAL PROBIOTIC”. WHAT DOES THIS MEAN?

A. Neuralli, a medical probiotic, is a type of medical food. A medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

Preclinical research shows that the PS128 probiotic strain in Neuralli is able to influence brain serotonin and dopamine as well as gut serotonin.^{5,6} Neurotransmitters including dopamine or serotonin are often dysregulated in neurodevelopmental conditions such as autism.^{7,8,9,10} Three clinical studies in ASD showed additional clinical improvement using PS128. Although PS128 was sourced from a fermented food, it is not possible to obtain adequate amounts of the probiotic in food. PS128 provides distinct nutritional support for healthy gut microbe to brain signaling to support neurological symptoms.

Neuralli is specially formulated for its function as a medical food. It contains a highly concentrated form of a naturally occurring probiotic strain, packaged in an acid-resistant capsule. Neuralli delivers a clinically relevant amount of live PS128 into the intestinal lumen when taken orally.



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TOP HEALTH CARE PROVIDER QUESTIONS ANSWERED

Q. HOW LONG DOES IT TAKE TO SEE IMPROVEMENTS IN NEUROLOGICAL OR GI TRACT FUNCTION WHEN USING NEURALLI?

A. While some PS128 clinical study participants noted statistically significant improvements in as little as 4 weeks, it may take up to three months to start experiencing the benefits of Neuralli. Most often, Neuralli customers report gentle and incremental improvements. However, everyone's gut microbiome and gut-brain axis are unique, and the timing and effects from taking Neuralli will also be different for everyone. Some will feel immediate benefits, some will notice gradual changes over time, and for others, improvements may be less evident.

Q. HOW CAN SOMEONE PURCHASE NEURALLI?

A. Neuralli is available for purchase directly from the Bened Life website at <http://benedlife.com>.

Q. HOW SHOULD MY PATIENTS TAKE NEURALLI?

A. We recommend taking two capsules of Neuralli per day with water. This amount, 60 billion CFU, is the same amount of PS128 used in the clinical trials on ASD, Parkinson's, and anxiety. It is important for Neuralli to be taken regularly (each day), but the specific timing is flexible. The two capsules can either be taken together or at different times.

Q. ARE THERE SIDE EFFECTS FROM TAKING NEURALLI?

A. When taking Neuralli as directed, some people may experience mild gastrointestinal upset such as gas, bloating, or stool changes for up to a week, just as when starting any new probiotic. Reports of adverse effects by autistic patients taking PS128 in three clinical studies were very low and lower than adverse effects when taking placebo or other probiotics. If symptoms persist, we recommend that people consult with their health care provider.

REFERENCES

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Last revised 5/22/2023



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