

Neuralli® MP and Neurological Conditions

Neuralli MP is a medical probiotic providing 60 billion colony forming units (CFU) per serving 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 brain neurotransmitters such as serotonin and dopamine, modifying the gut microbiome, and altering gut microbial metabolites such as butyrate.



TOP HEALTH CARE PROVIDER QUESTIONS ANSWERED

Q.

WHAT INGREDIENTS ARE IN NEURALLI MP?

A.

Neuralli MP delivers a live probiotic bacterial strain in an acid-resistant capsule. Each two-capsule serving contains 60 billion CFU of the probiotic strain *L. plantarum* PS128.

Q.

IS NEURALLI MP SAFE TO TAKE?

A.

Neuralli MP is safe for consumption. PS128 and the other ingredients in Neuralli MP have been affirmed as GRAS (generally recognized as safe).

Q.

IS PS128 DIFFERENT FROM OTHER PROBIOTICS?

A.

Yes, *L. plantarum* PS128 in Neuralli MP is a unique psychobiotic strain. 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 MP 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.¹⁻⁴ In an observational “real world” study in ASD, PS128 demonstrated better effects than other probiotics as a group.⁵

TOP HEALTH CARE PROVIDER QUESTIONS ANSWERED

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

A. More than eight clinical studies using PS128 in a variety of neurological conditions have been conducted as of 2024. Three randomized controlled clinical trials (RCTs) have been conducted with PS128 alongside existing prescribed treatments 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.⁶ A longer term RCT showed greater improvements when used in addition to another intervention.⁷ In a six-month “real-world” study,⁵ 87% of Autistic participants taking PS128 daily showed improvement, including increased shared attention, communication skills and personal autonomy. In the most recent study, an RCT in preschool-age Autistic children, physicians observed a reduction in anxiety after two months comparing PS128 to placebo.⁸

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 using PS128 as a nutritional add-on to their regular levodopa medication, a majority of participants reported significant improvements in motor symptoms, “off” time, and quality of life.⁹

A group of researchers reported greater anxiety reduction when PS128 was taken alongside citalopram versus taking citalopram alone, in a group of people with anxiety disorder.¹⁰ All of these trials used 60 billion CFU of PS128.

Q. HOW SHOULD MY PATIENTS STORE NEURALLI MP?

A. Refrigeration of the product is highly recommended to retain the highest potency. For best results, Neuralli MP 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 MP retain the highest potency through the Best By date. If Neuralli MP 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 MP IS A “MEDICAL PROBIOTIC.” WHAT DOES THIS MEAN?

A. Neuralli MP, 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.”

Growing evidence suggests that the increasing rates of many conditions and diseases, including neurological ones, may be associated with disturbances in gut microbiota, alterations in the gut-brain axis, and lack of certain microbes that have functions beyond the gut.^{11,12} This evidence suggests that we may need certain microbes, especially in the case of neurological conditions such as ASD and PD that also often have gut problems like constipation and have altered amino acid metabolism and/or serotonin metabolism related to microbial differences.^{13,14}

Although PS128 was sourced from a unique batch of a fermented food, it is not possible to obtain adequate amounts of the probiotic from food. PS128 provides distinct nutritional support for healthy gut microbe-to-brain signaling to support neurological conditions with clinically-meaningful outcomes. Neuralli MP 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 MP delivers a clinically relevant amount of live PS128 (60 billion CFU) into the intestinal lumen when taken orally.

TOP HEALTH CARE PROVIDER QUESTIONS ANSWERED

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

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 MP. From 472 customer survey responses from Oct 2023 to August 2024,[†] 51% saw an improvement before two months (this statistic includes a majority seeing improvement within the first month). Most often, Neuralli MP 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 MP 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 MP?

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

Q. HOW SHOULD MY PATIENTS TAKE NEURALLI MP?

A. We recommend taking two capsules of Neuralli MP 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 MP 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 MP?

A. When taking Neuralli MP 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 four 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.

Q. ARE THERE ALLERGENS IN NEURALLI MP?

A. Neuralli MP is formulated without milk, eggs, fish (mackerel, salmon roe, squid, salmon), crustacean shellfish (shrimp, crab), tree nuts (walnut, cashew nuts, almond), peanuts, wheat, soy, and sesame. It is also not made with chicken, pork, gelatin, abalone, squid, beef, seafood, soba, matsutake mushroom, peach, yam, apple, orange, kiwi fruit, or banana. Non-GMO corn maltodextrin is used in the manufacturing of *L. plantarum* PS128.

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[†]Survey conducted online Q4 2023 to Q3 2024 by Bened Life.

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