

## BioPro Calm



## Clinical Applications

- Supports a Healthy Mood and Well-Being\*
- Promotes a Healthy Stress Response\*

*BioPro Calm features *Lactobacillus paracasei* Lpc-37®, a signature probiotic strain clinically evidenced to support a relaxed state of mind and diminish perceived stress. This formula works within the gut microbiome to influence the physiological stress response.\**

All Focal Formulas Meet or Exceed cGMP Quality Standards

## Discussion

In the 1930s, pioneering endocrine researcher Hans Selye defined stress as “the non-specific response of the body to any demand made upon it.”<sup>1</sup> It is now well-documented that stress can cause detrimental effects on physical and mental health. In addition to the apprehension often associated with stress, daily stress can manifest symptoms, such as headaches and gastrointestinal distress, and lead to a lack of concentration and loss of sleep.<sup>2-4</sup> According to a pre-pandemic report from the American Psychological Association, nearly three-quarters of the surveyed adults older than 22 years and 9 in 10 young adults between 18 and 21 years reported experiencing at least 1 physical or emotional manifestation of stress in a given month.<sup>5</sup>

Physiologically, an acute stress response disrupts normal homeostasis through the activation of the hypothalamic-pituitary adrenal (HPA) axis, a process that culminates in the production of cortisol triggering the body’s fight-or-flight response. Chronic daily stress exposure impacts mental health—a dysregulation of the neuroendocrine response occurs that plays a role in the development of stress-related psychological issues. Prolonged stress has also been associated with biological changes that impact the composition of the gut microbiota. The gut is linked to the central nervous system through a communication system known as the microbiota-gut-brain axis, a complex network of pathways that is greatly impacted by stress.<sup>2,6</sup> The gut microbiome influences brain physiology and psychological response through a regulatory immune function involved with neuroinflammation, neurodevelopment, and the neuroendocrine stress response. The link between the gut microbiome and how its modification may impact stress responses has become an important area of research.<sup>7</sup>

Certain strains of bacteria have been shown to alleviate stress-related adverse effects in rodents exposed to chronic stress. In an experimental study, 12 probiotic strains from 10 species/subspecies of *Bifidobacterium* and *Lactobacillus* were assessed for their effect on behavior and neuroendocrine response in non-stressed and chronically stressed mice. In addition to a battery of behavioral tests, corticosterone and adrenocorticotropic hormone (ACTH) were analyzed. Of 12 probiotics used, *L. paracasei* (Lpc-37)<sup>‡</sup> and *L. plantarum* (LP12151, LP12407, and LP12418) diminished stress-associated behaviors, but Lpc-37 was the only strain that affected stress-associated deficits in mental focus. The researchers concluded that the beneficial effects on stress-related behavior vary and are species- and strain-specific.<sup>6</sup>

A randomized, double-blind, placebo-controlled trial known as the Sisu study was designed to investigate the effect of Lpc-37 on modulating stress, mood, and well-being in humans. Healthy adult subjects (N = 120) were stratified according to sex and either low or high chronic stress, and they were randomly assigned to 1.75 × 10<sup>10</sup> (17 billion) colony-forming units (CFU) of Lpc-37 or placebo (1:1) per day for 5 weeks following a 2-week washout period. Stress biomarkers were measured at baseline and study completion, and sleep quality, mood, and overall well-being were recorded throughout the study via an online daily diary. Researchers found that perceived stress was significantly reduced (*P* = .048) in subjects taking Lpc-37 using the perceived stress scale results. Significant additional effects were identified within the subgroups: Lpc-37 reduced exhaustion during the Trier Social Stress Test (TSST), normalized evening cortisol levels in participants with low chronic stress, and increased perceived health and sleep-related recovery in participants with high chronic stress. The results of the Sisu study indicated that Lpc-37 is an efficacious probiotic strain that impacts outcomes related to physiological and psychological stress in healthy adults.<sup>7</sup> To reaffirm the results of the Sisu trial, an in-home use test was conducted on 190 self-proclaimed healthy yet stressed consumers who took 17 billion CFU of Lpc-37 or placebo for 8 weeks. At baseline, at 4 weeks, and at the study conclusion (8 weeks), participants completed a line scale to assess stress levels and a Likert scale to assess stress and mental focus. The in-home use test reaffirmed the clinical trial results, which suggested a strong trend (~18%) toward lower stress levels in the active group compared with the placebo (~5%) group.<sup>8</sup>

In addition to being studied for its impact on managing psychological responses to stress, Lpc-37 has a long history of safe use, is well-suited for intestinal survival, has exhibited strong adhesion to intestinal cell lines, and has inhibited pathogens.<sup>9,10</sup> Additionally, it has been suggested in a recent animal study that Lpc-37 plays a role in alleviating memory impairments in sleep-deprived rodents. These findings require further research to assess if the same effects occur in humans.<sup>11</sup>

**BioPro Calm** provides probiotics that work within the gut microbiome to influence the physiological stress response.\*

<sup>‡</sup>*Lactobacillus paracasei* Lpc-37®, the probiotic strain referred to in this study, has been reclassified as *Lactobacillus paracasei* Lpc-37®.

## Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 30

	Amount Per Serving	%DV
<i>Lactocaseibacillus paracasei</i> Lpc-37 <sup>S1</sup>	43.75 mg (17.5 Billion CFU <sup>†</sup> )	**

\*\* Daily Value (DV) not established.

**Other Ingredients:** Microcrystalline cellulose, capsule (hypromellose, gellan gum, and water), silica, and ascorbyl palmitate.

† Colony-Forming Unit

S1. FloraFIT<sup>®</sup> is a registered trademark of DuPont or its affiliates.

## Directions

Take one capsule daily, or use as directed by your healthcare professional.

Consult your healthcare professional before use. Individuals taking medication should discuss potential interactions with their healthcare professional.

## Formulated To Exclude

Wheat, gluten, corn, yeast, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, sesame, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, and artificial preservatives.

## References

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\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.