ADVANCED Naturals

PRODUCT MONOGRAPH

FloraMED

(NPN 80013151)

Product composition

Medicinal Ingredients:

Each tablet contains:

Probiotic blend	6 billion CFU
Providing	
Lactobacillus acidophilus Nx5864	2.7 billion cfu
Bifidobacterium bifidum Nx5860	2.1 billion cfu
Lactobacillus rhamnosus Nx5839	300 million cfu
Lactobacillus salivarius Nx5863	300 million cfu
Bifidobacterium longum Nx5846	300 million cfu
Lactobacillus casei Nx5858	300 million cfu

Non-medicinal ingredients: Cellulose, pectin, sodium bicarbonate, sodium carbonate, silicon dioxide, stearic acid, turmeric (color).

Recommended dose: Adults and adolescents: Take 1 tablet daily with water on an empty stomach. Do not chew or crush.

Duration of use: None

Indication:

- Probiotic that forms part of a natural healthy gut flora.
- Provides live microorganisms that form part of a natural healthy gut flora.
- Probiotic that contributes to a natural healthy gut.
- Provides live microorganisms that contribute to a natural healthy gut flora.
- Probiotic to benefit health and/or to confer a health benefit.
- Provides live microorganisms to benefit health and/or to confer a health benefit.

Contraindications: Do not use if you are experiencing nausea, fever, vomiting, bloody diarrhea or severe abdominal pain. Do not use if you have an immune-compromised condition (eg. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment).

Warnings: Keep out of reach of children.

Precautions: Discontinue use and consult a health care practitioner if symptoms of digestive upset (e.g. diarrhea) occur, worsen, or persist beyond 3 days.

Adverse Effects: None

Overdose: For management of suspected product overdose it is recommended to contact your physician.

Symptoms of Overdose: Has not been investigated nor any reports have been filed.

Supporting Research and Traditional Evidence

Lactobacillus acidophilus Nx5864

Lactobacillus acidophilus is naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to contribute to a healthy gut. One study was conducted in which patients were treated with *B. bifidum* and *L. acidophilus* in an attempt to maintain a healthy intestinal flora during antibiotic treatment. Results suggested that the probiotic-treated group recolonized faster than the placebo-controlled group indicating that taking *L. acidophilus* as a daily supplement can help with the maintenance of a healthy intestinal flora (Black *et al.*1991). A randomized, double-blind, placebo-controlled study by Beausoleil *et al*. (2007) found similar results when patients were treated with *L. acidophilus* and *L. casei* in fermented milk along with an antibiotic. The administration the probiotic maintained a healthy intestinal flora. Furthermore, a study was conducted to assess the effects of *L. acidophilus* on stress-induced intestinal flora changes. Seventy-five healthy individuals were given approximately 1.5 × 109 cfu of *L. acidophilus* daily as probiotic therapy. Stress induced-gastrointestinal symptoms were assessed and compared to stress-related symptoms in the placebo-controlled group. Results suggested that treatment with probiotic therapy helped to reduce the disruption of the natural intestinal flora (Diop *et al*. 2008). The World Health Organization (2002) and the NHPD (2009) have reported *Lactobacillus acidophilus* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Bifidobacterium bifidum Nx5860

Bifidobacterium bifidum is naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to contribute to a healthy gut flora. Studies have been conducted to assess the efficacy of bacterial cultures as probiotics (Picard *et al.* 2005). A randomized study by Kirpich *et al.* (2008) assessed the effects of administering a dietary supplement containing *B. bifidum* to alcoholics. Alcohol consumption has been known to disrupt the intestinal flora. The study suggested that doses of 0.9 × 108 cfu for 5 days in combination with another probiotic, *Lactobacillus plantarum* helped promote restoration of a healthy gut flora. Secondly, a double-blind placebo-controlled study was conducted in which patients were treated with *B. bifidum* and *L. acidophilus*, a combination of two species present in FloraMED, in an attempt to maintain a healthy intestinal flora during antibiotic treatment. Results suggested that the probiotic-treated group recolonized faster than the placebo-controlled group indicating that taking a combination of *B. bifidum* and *L. acidophilus* as a daily supplement can help with the maintenance of a healthy intestinal flora (Black *et al*.1991). The World Health Organization (2002) and the NHPD (2009) have reported *Bifidobacterium bifidum* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Lactobacillus rhamnosus Nx5839

Lactobacillus rhamnosus are naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to promote a healthy gut flora. A placebo-controlled double-blind trial was conducted to assess the efficacy of *L. rhamnosus* in contributing to a healthy intestinal flora. This small-scale three-arm study evaluated the effects of ingestion of a low-fat spread containing 5 x 109 cfu or more of *L. rhamnosus*/day for 3 weeks. Fecal samples were provided by the 47 participants and evaluated for probiotic content. The results indicated that probiotic levels were significantly increased when compared to the placebo-control group (Dommels *et al.* 2009). In a second double-blind placebo controlled study, Wenus *et al*. (2008) assessed the effect of a combination probiotic treatment on the prevention diarrhea and restoration of the intestinal flora. Eighty-seven patients suffering from diarrhea were given a probiotic-enhanced milk supplement fermented with *Lactobacillus rhamnosus*, *Lactobacillus acidophilus*, and *Bifidobacterium Bb-12* at a dose of 25 x 108 to 25 x 109 CFU or more per day. The results indicated that antibiotic-associated diarrhea was reduced 79% in the probiotic-treament group when compared to the placebo-controlled group. The study

suggests that a combination of probiotic cultures can restore the disruption of the gut flora (Wenus *et al.* 2008). The World Health Organization (2002) and the NHPD (2009) have reported *Lactobacillus rhamnosus* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Lactobacillus salivarius Nx5863

Lactobacillus salivarius are naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to maintain a healthy gut flora. A randomized placebo-controlled study was conducted by Sierra *et al.* (2010) to assess the efficacy of *Lactobacillus salivarius* to maintain a healthy intestine. Forty healthy subjects were given a dose of 2 x108 cfu *L. salivarius*/day and the presence of probiotic culture in the fecal matter of the patients was assessed. The results suggested that treatment with *L. salivarius* at recommended doses helped contribute to a healthy gut flora (Sierra *et al.* 2010). The World Health Organization (2002) and the NHPD (2009) have reported *Lactobacillus salivarius* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Bifidobacterium longum Nx5846

Bifidobacterium longum are naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to promote a healthy gut flora. Studies have been conducted to assess the efficacy of bacterial cultures as probiotics.

A double-blind placebo-controlled study assessed the effects of probiotics on the maintenance of intestinal flora in 209 elderly people. The patients were administered a dose of 109 cfu/day of *B. longum* in an oat-based beverage. The results of the study suggest that *B. longum* when taken as a daily dietary supplement helps to modulate a healthy gut flora (Ouwehand *et al.* 2008). A second study assessed the effects on a combination probiotic therapy on bacterial colonisation of the intestine. Patients in remission from ulcerative colitis were given a combination of *B. longum*, *B. infantis*, *B. breve*, *L. acidophilus*, *L. casei*, *L. delbrueckii subsp bulgaricus*, *L. plantarum* and *Stretptococcus salivarius subsp thermophilus*. The probiotic combination was administrated at 1.5 x 1012 cfu/day and microbial content of the fecal matter was analyzed. Microbial analysis shows that intestinal probiotic levels were significantly increased when compared to baseline levels suggesting that treatment with combination a probiotic formula contributes to a healthy intestinal flora (Venturi *et al.* 1999).The World Health Organization (2002) and the NHPD (2009) have reported *Bifidobacterium longum* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Lactobacillus casei Nx5858

Lactobacillus casei are naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to confer a healthy gut flora.

A double-blind, placebo-controlled, randomized, parallel clinical trial was conducted to evaluate the efficacy of *L. casei* in the treatment of constipation in children as compared with magnesium hydroxide, a known laxative. Forty-five chronically constipated children were given either 50 mg/kg per day magnesium hydroxide, 8 × 10 8 cfu *L. casei*/day or placebo. Fecal samples were collected from the patients and analyzed for *L. casei* content. The results indicated a significant increase in probiotic prevalence in the feces and decrease in symptoms associated with constipation following continual treatment with *L. casei* suggesting that the probiotic was as effective as magnesium hydroxide in treating constipation. Secondly, a randomized, double-blind, placebo-controlled study was performed to assess the effects of a combination therapy of *L. casei* and *L. acidophilus*, two species of bacteria present in FloraMED, in maintaining the natural gut flora following treatment with an antibiotic. The researchers observed that patients receiving probiotics experienced a significant reduction in antibiotic-associated diarrhea, and thus maintained their natural intestinal flora (Beausoleil *et al.* 2007). The World Health Organization (2002) and the NHPD (2009) have reported *Lactobacillus casei* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Ingredient Summary

Lactobacillus acidophilus Nx5864
- Helps to maintain a healthy intestinal flora.

Bifidobacterium bifidum Nx5860
- Helps to restore a healthy gut flora.

Lactobacillus rhamnosus Nx5839
- Helps to restore natural intestinal flora.

Lactobacillus salivarius Nx5863
- Contributes to a healthy natural gut flora.

Bifidobacterium longum Nx5846
- Helps to modulate a healthy intestinal flora.

Lactobacillus casei Nx5858
- Contributes to a healthy natural gut flora.

References

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