Ultimate FloraMAX

(NPN 80015173)

ADVANCED Naturals

PRODUCT MONOGRAPH

Product composition
Medicinal Ingredients:
Each capsule contains:
Bifidobacterium bifidum (HA 132) …….....25 billion cfu
Bifidobacterium breve (HA 129) …….....4 billion cfu
Bifidobacterium longum (HA 135) ……. .....1 billion cfu
Lactobacillus acidophilus (HA 122) …….....10 billion cfu
Lactobacillus casei (HA 108) ……. .....8.875 billion cfu
Lactobacillus fermentum (HA 179) ……. .....250 million cfu
Lactobacillus plantarum (HA 119) ……. .....250 million cfu
Lactobacillus rhamnosus (HA 111) ……. .....250 million cfu
Lactobacillus rhamnosus (HA 114) ……. .....250 million cfu
Lactobacillus salivarius (HA 118) ……. .....125 million cfu

Non-medicinal ingredients: Hypromellose, cellacefate, phthalic acid, diethyl ester, fructooligosaccharides (FOS), ascorbic acid, stearic acid

Recommended dose: Adults: Take 1 capsule per day, approximately 2 hours after food.

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

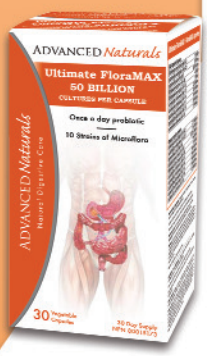
Bifidobacterium bifidum (HA 132)
Bifidobacterium bifidum is naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to contribute to a healthy gut flora. Studies have been conducted to assess the efficacy of bacterial cultures as 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* also present in this formulation of Ultimate FloraMAX, helped promote restoration of a healthy gut flora. A double-blind placebo-controlled 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 *B. bifidum* and *L. acidophilus*, a combination found in this formulation, 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.

Bifidobacterium breve (HA 129)
Bifidobacterium breve is also naturally present in the intestinal flora of healthy adults. When taken in recommended doses, these bacteria have been suggested to confer a healthy intestinal flora. Studies in patients suffering from enterocolitis have been conducted to assess the impact of taking *B. breve* and *L. casei*, another bacterial culture present in Ultimate FloraMAX, on maintaining a healthy gut flora. Associated with enterocolitis is the disruption of the gut flora. Seven patients were treated with over 3 x 109 of each bacterial type daily for an average of 36 months. Improvements in the maintenance of a normal intestinal flora were observed as determined by bacteria levels within the patients' fecal matter (Kanamori *et al.* 2004). A second study assessed the effects on a combination probiotic therapy on probiotic 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*, which are present in this formulation of Ultimate FloraMAX with the exception of *B. infantis*, *L. delbrueckii* and *S. salivarius*. The bacterial combination was administrated at 1.5 x 1012 cfu/day and the microbial content of the fecal matter was analyzed. Fecal analysis shows that intestinal bacterial levels were significantly increased when compared to baseline levels suggesting that combination probiotic treatment contributes to a healthy intestinal microflora (Venturi *et al.* 1999). The World Health Organization (2002) and the NHPD (2009) have reported *Bifidobacterium breve* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Bifidobacterium longum (HA 135)
Bifidobacterium longum is 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*, which are present in this formulation of Ultimate FloraMAX with the exception of *B. infantis*, *L. delbrueckii* and *S. salivarius*. 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 bacterial 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 acidophilus (HA 122)
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 *L. acidophilus* when taken 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. Another 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.

Lactobacillus casei (HA 108)
Lactobacillus casei is 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.
Studies in patients suffering from enterocolitis have been conducted to assess the impact of taking *L. casei* and *B. breve*, another bacterial culture present in Ultimate FloraMAX, on maintaining a healthy intestinal flora. One of the major symptoms associated with enterocolitis is the disruption



of the gut flora. Seven patients were treated with over 3 x 109 of each bacterial type daily for an average of 36 months. Improvements in the maintenance of a normal intestinal flora were observed as determined by bacteria levels within the patients' fecal matter (Kanamori *et al.* 2004). Secondly, a randomized, double-blind, placebo-controlled study was performed to assess the effects of a combination therapy of *L. casei* and *L. acidophilus* to maintain 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.

Lactobacillus fermentum (HA 179)

Lactobacillus fermentum 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 *L. fermentum* on promoting a healthy gut flora. A 2 week double blind randomized placebo controlled study was conducted in healthy subjects. Each participant was given a dose of 11.2 -11.8 log cfu of *L. fermentum* daily and fecal samples were analyzed for bacterial count. Treatment with *L. fermentum* resulted in an increase in lactobacilli in the feces of healthy individuals suggesting that *L. fermentum* contributes to a healthy intestinal flora when given in recommended oral doses (Songisepp *et al.* 2005). The World Health Organization (2002) and the NHPD (2009) have reported *Lactobacillus frementum* as a beneficial supplement with a good safety profile to contribute to a natural healthy gut flora.

Lactobacillus plantarum (HA 119)

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

A randomized study by Kirpich *et al.* (2008) assessed the effects of administering a dietary supplement containing *L. plantarum* to alcoholics. Alcohol consumption has been known to disrupt the intestinal flora. The study suggested that doses of 0.9 × 109 cfu for 5 days in combination with another probiotic, *Bifidobacterium bifidum*, also present in this formulation of Ultimate FloraMAX, helped promote restoration of a healthy gut flora. A randomized double-blind placebo-controlled study was conducted to assess the effects of a dietary supplement containing *L. plantarum* after disruption of the intestinal flora by antibiotic treatment. The bacterial dose given to 163 participants was 5×107 cfu/day in the form of an oat gruel. The prevalence of diarrhea was decreased in the probiotic-treatment group suggesting that oral treatment with *L. plantarum* helped to recolonize the intestine and reduce antibiotic-associated diarrhea (Lonnermark *et al.* 2010). The World Health Organization (2002) and the NHPD (2009) have reported *Lactobacillus plantarum* as a beneficial supplement with a good safety profile which contributes to a natural healthy gut flora.

Lactobacillus rhamnosus (HA 111/HA 114)

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. Fifty-five patients with irritable bowel syndrome were given a placebo or probiotic supplement containing 2 strains of *L. rhamnosus*, 1 strain of *B. breve*, and 2 bacterial species not present in Ultimate FloraMAX, daily for 6 months. Fecal samples from the participants were analyzed for bacterial content to measure the effects of probiotcs on the intestinal flora. The results of the study indicated the presence of the probiotics in the fecal matter of the participants suggesting that the administration combination probiotics daily can contribute to healthy intestinal flora (Kajander *et al.* 2007). 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 109 to 25 x 108 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. This suggests that the combination 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 (HA 118)

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 to contribute to a natural healthy gut flora.

Ingredient Summary

Bifidobacterium bifidum (HA 132)
- Helps to restore a healthy gut flora.

Bifidobacterium breve (HA 129)
- Contributes to a natural intestinal flora

Bifidobacterium longum (HA 135)
- Helps to modulate a healthy intestinal flora.

Lactobacillus acidophilus (HA 122)
- Helps to maintain a healthy intestinal flora.

Lactobacillus casei (HA 108)
- Contributes to a healthy natural gut flora.

Lactobacillus fermentum (HA 179)
- Helps to maintains a natural intestinal flora.

Lactobacillus plantarum (HA 119)
- Contributes to a healthy gut flora.

Lactobacillus rhamnosus (HA 111/HA 114)
- Helps to restore natural intestinal flora.

Lactobacillus salivarius (HA 118)
- Contributes to a healthy natural gut flora.

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