

PRO-FLORA™ WOMEN'S PROBIOTIC LACTOBACILLUS RHAMNOSUS GR-1® AND LACTOBACILLUS REUTERI RC-14®

Maintaining balanced microflora has a profound influence on women's health. Numerous factors influence the balance of vaginal microflora, including vaginal pH, hormonal changes, stressors, direct exogenous exposures, and diet. *Lactobacilli* species help promote a healthy vaginal environment through many mechanisms, including the production of hydrogen peroxide, which helps maintain an acidic pH, and the production of bacteriocins, which inhibit the growth of less beneficial organisms.*

Clinically Proven for Vaginal Health*

Pro-Flora Women's Probiotic is a combination of two proprietary, clinically proven *Lactobacillus* strains, *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14, that are supported by more than 20 years of clinical research in supporting urogenital health.*¹⁻³ Research shows that the combination of GR-1 and RC-14:*

- Is proven to colonize the vaginal tract after oral administration*
- Helps restore and maintain a healthy balance of vaginal microflora and yeast*
- Promotes healthy bacterial and yeast balance*
- Safe to use with conventional options for urogenital health*
- Safe for use by pregnant women



gluten free



soy free



1. Reid G, Charbonneau D, Erb J, et al. *FEMS Immunol Med Microbiol* 2003;35:131-4.
2. Anukam KC, Osazuwa E, Ahonkhai I, et al. *Microbes Infect* 2006;8:1450-4.
3. McMillan A, Dell M, Zellar MP, et al. *Colloids Surf B Biointerfaces* 2011;86:58-64.

PRO-FLORA™ WOMEN'S PROBIOTIC

Background

A healthy balance of vaginal microflora is an essential part of women's health. Approximately 10% of women's visits to healthcare professionals are related to support of vaginal comfort and normal vaginal odor.¹ Women of reproductive age are those most frequently needing support to achieve a healthy microbial balance of their vaginal ecosystem.²

Lactobacilli That Support Healthy Vaginal Ecology

Vaginal flora are a closely-related subset of the flora inhabiting the intestinal tract. However, not all *Lactobacilli* colonize the vagina or are effective at balancing the vaginal flora. *Lactobacillus acidophilus* and *L. rhamnosus* GG, for example, are not effective for this purpose.³ A healthy vaginal ecosystem is dominated by specific *Lactobacilli*, including *L. iners*, *L. crispatus*, *L. acidophilus*, *L. rhamnosus*, and *L. reuteri*.⁴ Other organisms found in the normal vaginal ecosystem include *E. coli*, *C. albicans*, mycoplasmas, *Streptococcus* species, *Staphylococcus* species, and *Gardnerella vaginalis*.¹

Lactobacilli help maintain a healthy vaginal environment via numerous mechanisms. They compete with other organisms for adherence and nutrients, and they support a healthy vaginal pH in the range of 3.8–4.5, mainly through their production of hydrogen peroxide.⁵ Certain *Lactobacilli* can produce bacteriocins, substances that control the growth of closely related but less beneficial bacteria.⁶ Some *Lactobacilli* beneficially alter the composition of microbial biofilms of the vaginal ecosystem.⁷

Pro-Flora™ Women's Probiotic

Pro-Flora Women's Probiotic is a combination of two proprietary, clinically-proven *Lactobacillus* strains, *Lactobacillus rhamnosus* GR-1® and *Lactobacillus reuteri* RC-14®, that are supported by more than 20 years of clinical research.

- Helps colonize the vaginal tract after oral administration*⁸
- Helps restore and maintain healthy balance of vaginal microflora*^{7,9,10}
- Promotes healthy bacterial and yeast balance*³
- Supports healthy vaginal comfort and odor*^{3,11}
- Safe to use with conventional options for urogenital health*¹¹

Pro-Flora Women's Probiotic Clinical Trials

More than 20 published clinical trials have demonstrated the safety and efficacy of the GR-1 and RC-14 combination.^{3,8–16} These proprietary strains offer support for healthy vaginal microflora balance, alone or in synergy with conventional agents; support accurate cervical cytology; and support bowel health and regularity.*^{3,11–13}

Canadian researchers isolated two vaginal strains of *Lactobacillus*: *L. rhamnosus* GR-1 and *L. reuteri* RC-14 (previously *L. fermentum* RC-14). A randomized, placebo-controlled clinical trial demonstrated vaginal colonization following oral administration to 64 healthy women. Participants took a capsule containing GR-1 and RC-14, or a matching placebo, once per day for 60 days. The combination was found to significantly and beneficially alter the vaginal flora.* Culture findings confirmed a significant increase in *Lactobacilli* at day 28 and day 60.* At day 28, individuals who received GR-1 and RC-14 demonstrated improved yeast balance.*³

Another study sought to determine the dose of GR-1 and RC-14 needed to effectively balance the vaginal microflora. Forty-two healthy women were randomized to receive 1 of 3 dosages of a combination of GR-1 and RC-14 for 28 days: 800 million Colony Forming Units (CFU) once daily, 800 million CFU twice daily (1.6 billion daily), or 6 billion CFU once daily. A control group received 10 billion CFU *L. rhamnosus* GG. Up to 90% of women who received the GR-1/RC-14 combination demonstrated improved vaginal microflora balance, while those receiving *L. rhamnosus* GG did not benefit.* Benefits were greatest in those receiving 800 million CFU twice daily (1.6 billion CFU daily).⁹

The combination of GR-1 and RC-14 has also demonstrated benefits in promoting balanced vaginal flora in a study of 72 postmenopausal women.* Women in the intervention group received 1 capsule containing GR-1 and RC-14 each day for two weeks, while women in the control group received an oral placebo. Twenty-one of the 35 subjects (60%) in the intervention group and 6 of the 37 subjects (16%) in the control group showed significant improvement in vaginal ecology scores.* The difference in the number of patients with improvement was highly significant ($p=0.0001$).¹⁴

Synergy with Conventional Options

GR-1 and RC-14 enhance the efficacy of conventional options in supporting women's urogenital health.*^{11,15}

In a double-blind, placebo-controlled, randomized clinical trial, 125 premenopausal women (ages 18–44) received a conventional oral agent twice daily for 7 days. They received one capsule containing GR-1 and RC-14, or placebo, twice daily for 30 days. At the study's end, only 40% receiving the conventional agent alone demonstrated normal vaginal microbial balance, compared with 88% of women who also received the GR-1/RC-14 combination.* Methods of assessment included microscopic examination of vaginal fluid samples, an enzyme associated with certain microflora, and patient comfort.*¹¹

In a randomized, double-blind, placebo-controlled clinical trial, 55 women received a single dose of a conventional agent to support healthy yeast balance as well as two capsules of *L. rhamnosus* GR-1 and *L. reuteri* RC-14, or matching placebo, once daily for 28 days. Probiotic supplementation helped optimize yeast balance, with a greater number of individuals in the placebo group seeking further support for yeast balance at the study's end, versus the probiotic group (38.5% vs. 10.3%).*¹⁵

Support for Accurate Cervical Cytology

Numerous factors influence the accuracy of cervical cytology screening, including proper collection, preparation, and analysis of cells, as well as vaginal microbial balance. Two hundred-fifty women receiving conventional care for vaginal microbial balance were divided into two groups, with half receiving GR-1 and RC-14 for 4 weeks. At the study's onset and at 6 weeks, cervical smear cytology was performed. Supplementation with GR-1 and RC-14 supported normal cervical cell structure and function, and also improved the accuracy of cervical cell cytology screening.*¹²

Gastrointestinal Support

L. rhamnosus GR-1 and *L. reuteri* RC-14 have also been shown to support bowel health and regularity.* Twenty-four women with occasional loose stools, gas, and nausea were randomized to receive either plain yogurt or yogurt supplemented with GR-1 and RC-14 for 15 days. All 12 of the probiotic-supplemented women experienced resolution of their symptoms, compared with only 2 of 12 of those receiving unsupplemented yogurt.¹³

Complementary Measures for Urogenital Health

Lifestyle measures can complement GR-1 and RC-14 in maintaining women's urogenital health.* Safe sexual practices, particularly regular use of condoms, may help maintain a healthy vaginal pH. Vaginal douching, which depletes *Lactobacilli* from the vaginal tract, should be avoided. Vaginal administration of estrogen in postmenopausal women may help maintain a healthy, more acidic vaginal pH. Allergenic stimuli, such as food, pollen, and detergent, should be identified and avoided. Diet should be based on whole, unrefined foods with little or no refined carbohydrates or sugars.¹

Safety

Pro-Flora Women's Health is safe to use both on its own and in combination with conventional options for urogenital health.* *L. rhamnosus* GR-1 and *L. reuteri* RC-14 have been demonstrated to be safe for use by pregnant women.¹⁶

References

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Supplement Facts

Serving Size 1 capsule

Amount per capsule	%DV
<i>Lactobacillus rhamnosus</i> GR-1® and <i>Lactobacillus reuteri</i> RC-14®	1 Billion CFU† **

**Daily Value not established.

Other ingredients: maltodextrin, vegetable capsule (modified cellulose), cellulose, silicon dioxide, magnesium stearate, and titanium dioxide color.

†Clinically validated dosage. Each capsule contains a minimum of 5 billion CFU at time of manufacture. Potency and viability guaranteed at a minimum of 1 billion CFU through expiration date. May contain a minimal amount of residual milk protein.

Recommendations: Take 1 capsule daily. May be taken with or without food. May increase to 2 capsules daily as needed, or as recommended by your healthcare professional. Store in a cool, dry location. May refrigerate if desired. If taking prescription drugs, consult your healthcare professional prior to use. This product does not interfere with the efficacy or activity of commonly prescribed medications.

Contains no: sugar, salt, gluten, soy, artificial flavoring, or preservatives. All colors used are from natural sources.

Integrative Therapeutics	Natural Partners	Emerson Ecologics
30 CT - 70671	30 CT - IT0086	30 CT - IT70671

Indoplex®

Indoplex is a nutritional supplement containing a patented, bioavailable form of diindolylmethane (DIM®), a dietary indole naturally present in cruciferous vegetables. Research shows DIM promotes healthy estrogen metabolism by increasing the production of 2-hydroxyestrone estrogen metabolites over the undesirable 16-hydroxyestrone estrogen metabolites.*These critical metabolites have been shown to promote healthy cell development.*

- Features a patented form of DIM that is 10 times more potent than its precursor, indol-3 carbinol (I3C)
- Enhanced absorption and bioavailability

#286006, 30 Veg Capsules; #286002, 60 Veg Capsules; #75336, 60 Tablets



wheat free gluten free dairy free vegetarian



Cortisol Manager™

Cortisol Manager is a stress hormone stabilizer that combines phosphatidylserine with stress-reducing ingredients and botanicals to help reduce stress hormones and relieve occasional sleeplessness.* This supplement promotes relaxation and supports a healthy sleep cycle without the use of habit-forming ingredients.*

- Will not cause morning grogginess*
- Increases the ability to fall asleep and stay asleep, while also providing all-day stress reduction*†
- This fast-acting formula reduced cortisol by more than 60% after only 24 hours*†

#70453, 30 Tablets; #70459, 90 Tablets



wheat free gluten free corn free dairy free vegetarian



OsteoPrime® Ultra

OsteoPrime Ultra delivers balanced nutritional support to keep bones strong and resilient.* Formulated to include five forms of calcium, plus magnesium and trace minerals, such as strontium, this exclusive combination is ideal for female patients requiring a high level of bone support.*

- Developed in collaboration with Alan Gaby, MD, OsteoPrime Ultra includes 24 supportive vitamins, trace minerals, and other key nutrients*
- Features vitamin K2, a highly bioavailable form of vitamin K, which plays an important role in building bone*

#77712, 120 tablets



wheat free gluten free corn free



Indoplex® and DIM® are trademarks of and are licensed from BioResponse, L.L.C; U.S. Patent 6,086,915.

†An open label pilot study involving 21 volunteers of the safety and effectiveness of a cortisol-reducing combination in healthy adults. 2006. Unpublished.

*THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.