

DESIGN PHILOSOPHY:

Pre + Probiotic for Women

Perspective

- Women experience more gastro-intestinal distress and higher levels of intestinal inflammation than men.¹
- During a typical menstrual cycle, the intestines will alternatively speed up or slowdown in response to hormonal changes and inflammatory cues.²
- Menopause leads to increased intestinal permeability and higher inflammation.³
- Healthy intestinal microbiome supports vaginal and bladder health.^{4,5}
- Gut and intestinal dysbiosis increases significantly during aging, and this change is strongly related to reduced fiber consumption.⁶
- Altered gut microbiome associated with aging is linked to cognitive decline and increased rates of dementia.⁷
- Women are 2-3 times more likely to experience constipation than men.⁸
- Women are also more likely than men to develop Crohn's disease.⁹
- Women are more likely to experience dyspepsia than men, and a recent meta-analysis estimates 25% of women currently experience dyspepsia.¹⁰
- Altered intestinal microbiome and reduced fiber intake are strongly linked to dyspepsia.¹¹



What Pre+Probiotic is Not

Not alternative medicine. Pre+Probiotic For Women is grounded in science and published studies. It relies on clinical data, and is designed to be supported by rigorous clinical trials.

Not a cure. Pre+Probiotic For Women does not cure diseases, and will not claim to, but rather provides support for women wishing to support their intestinal health.

Not a quick fix. Changes to diet, environment and exercise are the best approaches to promote gastrointestinal health, and Pre+Probiotic For Women is designed to be a supportive addition to lifestyle changes.

Semaine Pre+Probiotic for women shows it is possible to rationally design a product that supports multiple physiological factors linked with improved gastrointestinal health and that does so in a safe manner.

Product Profile for Pre + Probiotic for Women

Design objectives

- Provide prebiotic fiber at levels that are supported by epidemiological studies and RCTs to improve intestinal health
- Provide a probiotic blend of safe and well-studied bacterial strains to support a healthy intestinal microbiome
- Provide ginger at levels that are supported by epidemiological studies and RCTs to improve dyspepsia and nausea

Product Formulation

Pre-biotic fiber blend

Rationale

- A significant challenge to intestinal health is the limited amount of prebiotic fiber that most people in the US consume.^{12,13}
- Providing both a pre + probiotic at the same significantly increases the health of the microbiome and helps the probiotic take hold.¹⁴
- Soluble fibers provide bulking agents for the intestines and has the ability moderate transit (improving constipation while also reducing diarrhea).¹⁵

Safety and tolerability

- Psyllium husks and acacia gum are extremely well tolerated by the general population.
- Psyllium husks and acacia gum are low FODMAP and have good tolerance among populations with IBS.¹⁶
- Higher doses (>1g) need to be consumed with a large glass of water.

Forms and dosage (per capsule)

- 250mg split between psyllium husk powder and organic acacia gum

Probiotic fiber blend

Rationale

- *Lactobacillus Acidophilus* & *Lactobacillus Plantarum* are two of the best studied probiotic strains with extensive safety profile.^{17,18}
- *Lactobacillus Acidophilus* has been shown to help with both intestinal health, and when taken orally, it has been shown to reduce rates of Bacterial vaginosis.^{18,19}
- *Lactobacillus Plantarum* has been shown to reduce intestinal inflammation as well as to reduce yeast infections.²⁰⁻²²

Safety and tolerability

- Very safe and tolerable.
- Given the extensive numbers of studies conducted with both strains, can have a higher degree of confidence that patients will not experience adverse events.

Forms and dosage (per capsule)

- Total of 2 billion CFU split between *Lactobacillus Acidophilus* & *Lactobacillus Plantarum*.

Ginger

Rationale

- Many customers who want a probiotic do so because they are experiencing intestinal issues, and have higher gut inflammation.⁴
- Ginger (and the active ingredients gingerols) are well documented to help lower inflammation in the intestine, and help with an upset stomach.²³⁻²⁵
- Heartburn is another common concern, and ginger has been shown to improve gastric emptying and reduce dyspepsia.²⁶
- Including gingerols helps the customer experience

a rapid improvement in their intestines after they begin the supplement

Safety and tolerability

- Ginger has an excellent safety profile. But at doses 5x higher than doses we use, it can cause stomach upset in a small number of patients.

Forms and dosage (per capsule)

- 120 mg of Ginger root extract standardized to 5% gingerols.
- This is equivalent to 1.5g of the whole root, which is commonly recommended for nausea.²⁷

Semaine Health Co. Philosophy

- Rooted in a patient- and advocacy-focused approach with deep relationships especially in the endometriosis community.
- Focused on continuous engagement with medical professionals to guide product development and provide useful information to customers.
- Committed to using clinical trials to validate claims. Results from the pilot study are included in this report.

References

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