



GYNECOLOGY

Formulation De Simone
High Dose Microbiotic



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for healthcare professionals**



Scientific information about
the De Simone Formulation (DSF)
www.probiotixx.info/en/hcp

What the studies say

“Contact with microbes begins in utero and proceeds in a stepwise manner during birth and early infancy. Early host–microbe interaction is a crucial component of healthy immune and metabolic programming. Mode of delivery, prematurity, perinatal antibiotic exposure and breastfeeding have a major influence on early microbial contact, intestinal colonization and subsequent risk of disease. Maternal probiotic supplementation during pregnancy and breastfeeding has shown potential in reducing the risk of immune-mediated and metabolic disease via modulation of early host–microbe interactions.”

Rautava S. et al Nature Reviews Gastroenterology & Hepatology 9, 565–576 (2012)

DSF (De Simone Formulation) and gynecology

- Helps restore the balance of the intestinal flora in women
- Helps restore the balance of the vaginal flora
- Supports in case of bacterial vaginosis
- Helps prevent urinary tract Infections

DSF and pregnancy

- Improves blood levels of folates and Vit B12
- Reduces blood levels of homocysteine
- Reduces inflammatory cytokines at vaginal level

DSF and birth

- Improves the quality of breast milk
- Reduces breast milk cytokines, increases breast milk TGF and sIgA in newborns
- Improves gastrointestinal functional symptoms in infants
- Reduces symptoms of infantile colics

Studies conducted with the De Simone Formulation (DSF)

Dietary supplementation with probiotics during late pregnancy: outcome on vaginal microbiota and cytokine secretion ⁽¹⁾

BMC Microbiol. 2012 Oct 18;12:236.

Beatrice Vitali, Federica Cruciani, Maria Elisabetta Baldassarre, Teresa Capursi, Enzo Spisni, Maria Chiara Valerii, Marco Candela, Silvia Turroni and Patrizia Brigidi

The activity of lactobacilli helps to maintain the natural healthy balance of the vaginal microbiota. This role is particularly important during pregnancy because vaginal dysmicrobism is one of the most important mechanisms for preterm birth and perinatal complications.

This controlled pilot study characterized the impact of a dietary supplementation with the probiotic DSF (De Simone Formulation), 900 Billion bacteria daily, on the vaginal microbiota and immunological profiles of 27 healthy women during late pregnancy (4 weeks).

Results: An association between the oral intake of the probiotic DSF and changes in the composition of the vaginal microbiota of pregnant women was revealed by PCR-DGGE population profiling. In addition, the probiotic consumption induced the decrease of the pro-inflammatory chemokine Eotaxin, suggesting a potential anti-inflammatory effect on the vaginal immunity.

Conclusion: Dietary supplementation with the probiotic DSF during the last trimester of pregnancy was associated to a modulation of the vaginal microbiota and cytokine secretion, with potential **implications in preventing preterm birth.**

A pilot study on the role of probiotic in the treatment of the bacterial vaginosis in pregnant women ⁽²⁾

Minerva Ginecol. 2013 Apr;65(2):215-21.

F. Facchinetti, G. Dante, L. Pedretti, P. Resasco, E. Annessi, D. Dodero

The aim of this randomized, placebo-controlled study was to compare the effects of a dietary supplementation with the oral probiotic DSF, and the treatment with vaginal clindamycin in 40 pregnant women with bacterial vaginosis.

Women were enrolled between the 10th and the 34th week of gestation. The patients were randomized in two groups.

Patients in the group A were treated with probiotic orally (DSF), 225 Billion bacteria per day for 5 days, followed by 112 Billion bacteria daily for 10 days.

Patients in group B were treated with vaginal clindamycin 100 mg daily for 15 days.

Conclusion: The oral treatment with **DSF is as effective in the treatment of BV in pregnant women** as a topical treatment with clindamycin. In particular for the resolution of leukorrhea, itching and bacterial vaginosis caused by Gardnerella V.

Administration of a multistrain probiotic product to women in the perinatal period differentially affects breast milk beneficial microbiota in relation to mode of delivery ⁽³⁾

Pharmacol Res. 2015 May-Jun;95-96:63-70.

Paola Mastromarino, Daniela Capobianco, Alfredo Miccheli, Giulia Praticò, Giuseppe Campagna, Nicola Laforgia, Teresa Capursi, Maria E. Baldassarre

The aim of our placebo-controlled double-blind randomized study was to evaluate the effect of oral supplementation with the probiotic DSF, during late pregnancy and lactation, on breast milk levels of beneficial bacteria and some functional components (oligosaccharides and lactoferrin) potentially able to have a positive influence on the microbiota.

In a double-blind, placebo-controlled, randomized trial, 66 women with Bacterial Vaginosis took daily either the probiotic DSF 900 Billion per day (n = 33) or a placebo (n = 33) from the 36th week of pregnancy until 4 weeks after giving birth.

The amounts of both lactobacilli and bifidobacteria were significantly higher in the colostrum and mature milk of the mothers taking DSF in comparison to those taking placebo.

In women with vaginal delivery, significantly higher amounts of lactobacilli and bifidobacteria were detected in colostrum and mature milk of probiotic treated group

Our results indicate a probiotic-dependent modulation of breast milk microbiota in vaginally delivering women, possibly **exerted through a systemic effect.**

Effects of a Multispecies Probiotic Mixture on Glycemic Control and Inflammatory Status in Women with Gestational Diabetes: A Randomized Controlled Clinical Trial⁽⁴⁾

J Nutr Metab. 2016;2016:5190846

Sadegh Jafarnejad, Sadaf Saremi, Farzan Jafarnejad, and Arman Arab

This double-blind randomized controlled study aims to examine the effects of a Probiotic Mixture (DSF) on glycemic status and inflammatory markers, in women with Gestational Diabetes Mellitus.

Over a period of 8 weeks, 82 women with GDM were randomly assigned to either an intervention group (n = 41) which were given DSF capsule (112.5 billion/capsule) or to a control group which were given placebo capsule (n = 41).

Fasting plasma glucose, homeostatic model assessment of insulin resistance, glycosylated hemoglobin, high-sensitivity C-reactive protein, tumor necrosis factor- α , interleukin-6, Interferon gamma, and interleukin-10 were measured before and after the intervention.

Conclusions: In women with GDM, supplementation with probiotics (DSF) may **help to modulate some inflammatory markers and may have benefits on glycemic control.**

Administration of a Multi-Strain Probiotic Product to Women in the Perinatal Period Differentially Affects the Breast Milk Cytokine Profile and May Have Beneficial Effects on Neonatal Gastrointestinal Functional Symptoms. A Randomized Clinical Trial⁽⁵⁾

Nutrients. 2016 Oct 27;8(11).

Maria Elisabetta Baldassarre, Antonio Di Mauro, Paola Mastromarino, Margherita Fanelli, Domenico Martinelli, Flavia Urbano, Daniela Capobianco and Nicola Laforgia.

The aim of the study was to evaluate the effect of DSF to women during late pregnancy and lactation on cytokine profile and secretory IgA (sIgA) in breast milk and thus to study if differences in breast milk composition can affect lactoferrin and sIgA levels in stool samples of newborns.

In a double-blind placebo-controlled randomized clinical trial, 66 women took either the probiotic DSF 900 billion/day (n = 33) or a placebo (n = 33) daily, 4 weeks before the expected delivery date (36th week of pregnancy) until 4 weeks after delivery.

Levels of interleukins (IL-6, IL-10 and IL-1 β), transforming growth factor- β 1 (TGF- β 1), and sIgA in breast milk; and the level of sIgA and lactoferrin in newborn stool samples were analyzed at birth and then again at one month of life.

Anthropometrical evaluation and analysis of gastrointestinal events in newborns was also performed.

Conclusion: DSF administration to women during pregnancy **influences breast milk cytokines pattern** and **sIgA production** in newborns and seems to **improve gastrointestinal functional symptoms** in infants.

Effect of administration of a probiotic preparation on gut microbiota and immune response in healthy women in India: an open-label, single-arm pilot study⁽⁷⁾

BMC Gastroenterol. 2018 Jun 15;18(1):85.

Ankita Singh, Aditya N. Sarangi, Amit Goel, Rajni Srivastava, Rajat Bhargava, Priyanka Gaur, Amita Aggarwal and Rakesh Aggarwal

The primary objective of this open-label single-arm pilot study was to assess the effect of 112 billion DSF, twice a day (total of 224 billion CFU/day) for 4 weeks in 14 healthy women on the profile of gut microbiota and immune response.

A secondary objective was to assess the persistence of these changes, if any, after 4 weeks.

Each subject provided morning stool and venous blood specimens at three time-points, i.e. at baseline (before probiotic administration), after probiotic administration and 4-weeks after discontinuation of the probiotic administration.

Conclusions: DSF administration led to a reduction in the frequency of Th17 cells and in the production of pro-inflammatory cytokine on lipopolysaccharide stimulation.

These findings suggest that **the beneficial anti-inflammatory effect** of this preparation in patients with autoimmune and allergic disorders may be related to **reduced production of monocyte-derived cytokines**.

Dosage Summary Table of clinical studies

Population	Duration	Intervention	Design
27 Healthy Pregnant Women ¹	4 weeks	900B CFU/day	a controlled, pilot study
40 Pregnant Women with Bacterial Vaginosis ²	15 days, follow-up occurred 5-10 days post treatment	225B CFU for 5 days and 112B CFU for 10 days	a randomized, placebo-controlled study
66 Pregnant Women ³	From the 36th week of pregnancy until 4 weeks after giving birth	900B CFU/day	a placebo-controlled, double-blind, randomized study
82 Women with Gestational Diabetes ⁴	8 weeks	112.5B CFU/day	a double-blind randomized controlled study
66 Mother/Newborn pairs ⁵	4 weeks before the expected delivery date	900 B CFU / day	a double-blind, randomized, placebo-controlled clinical trial
50 Obese Pregnant Nulliparous Women ⁶	From gestational age: 14–20 weeks until delivery	450B CFU/day	a randomized controlled pilot study
14 Healthy Women ⁷	For 4 weeks	225B CFU/day	an open-label, single-arm pilot study

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A member of the American College of Gastroenterology, Claudio De Simone is a retired Professor of Infectious Diseases of the University of L'Aquila (Italy), specialized in Gastroenterology, Allergology and Clinical Immunology. His interest in the human microbiota goes back more than 25 years when the understanding of the importance of the role of the intestinal flora was in its infancy.



The Letter of probiotics

THE BLOG OF A PIONEER IN PROBIOTICS

INFORMATION FOR HEALTHCARE PROFESSIONALS ONLY

The Letter of probiotics (probiotixx.info) is the blog of Prof. Claudio De Simone, a pioneer in the intestinal microbiota and inventor of a probiotic mixture (8 strains, 450 billion bacteria) known as the De Simone Formulation.

The information posted on this website is dedicated to healthcare professionals.

Important information brochures and updates on the action of probiotics and on the De Simone Formulation (studies and scientific publications on IBD, IBS, liver diseases, autism etc.) are available subject to registration in the Healthcare Professional section of Prof. De Simone's blog: :

LIVER DISEASES	IBD	IBS
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