BACKGROUNDER

Pregnitude®
A Fertility Dietary Supplement for Reproductive Support
Offers an Additional Option for Women Who Are Trying to Conceive

Studies find that increased chances of ovulation, menstrual regularity and higher egg quality rank among the product's benefits

Overview

Pregnitude is a fertility dietary supplement for reproductive support. The product originated in Italy eight years ago and has been found to be beneficial in several studies, summarized below. Pregnitude was introduced to the U.S. market in 2012 by Exeltis USA (formerly Everett Laboratories, Inc.) based in Florham Park, NJ.

The product is recognized as a viable first-line, non-prescription option for women who may be having difficulty getting pregnant. Some common reasons for the inability to conceive include:

- **Age:** While many women in the 30s and 40s have no problems getting pregnant, fertility declines after age 35 and changes to the ovaries and eggs make it harder for some women to become pregnant.
- **Lifestyle Factors:** Poor diet, smoking and high levels of stress, among other factors, can affect the menstrual cycle causing irregular ovulation.
- **Polycystic Ovarian Syndrome (PCOS)**: A complex, yet common health condition in women which has been reported to be a leading cause of difficulty conceiving.

Some leading physicians have recommended Pregnitude to women who want to consider a natural approach as a first step in their journey trying to overcome difficulties conceiving.

Dr. Scott Roseff is a principal author of a seminal review of Pregnitude as an option for addressing difficult conception. The article, "*New Options for Supporting Women Having Difficulty Conceiving*" was published in the peer-reviewed journal, The Female Patient. (www.jfponline.com/fileadmin/qhi_archive/ArticlePDF/TFP/037040001s.pdf) It states that "…given that the principal aim in a general ObGyn practice of managing patients having difficulty conceiving is to restore, or at least improve, ovulatory function, Pregnitude. . . appears to improve the conditions necessary to achieve that goal and may give ObGyns an additional tool toward achieving success in this patient population." Pregnitude may aide women who are trying to conceive by helping to support ovulatory function, promoting menstrual regularity and supporting the quality of eggs.

The challenge of delayed motherhood

In the US, more than six million women have difficulty becoming or staying pregnant – that's about 10 percent of women aged 15-44. Many women are waiting until their 30s and 40s to have children. In fact, about 20 percent of women in the United States now have their first child after age 35. So age is a growing cause of fertility problems. About one-third of couples in which the woman is over 35 have fertility problems.

Pregnitude contains myo-inositol (MI) and folic acid (FA), essential for healthy ovulatory function. MI is a naturally occurring substance produced by the human body from glucose, and FA is a B vitamin that is necessary for cell growth. Each single serving packet of Pregnitude contains 2,000 milligrams of MI and 200 micrograms of FA.

Controlled clinical studies have demonstrated that the ingredients found in this supplement have a beneficial effect on ovulatory function, improving ovulation frequency, promoting menstrual cycle regularity and improving the quality of oocytes, or eggs.

What the studies show

Several studies have been conducted on the efficacy of myo-inositol (and myo-inositol plus folic acid) in promoting menstrual cyclicity, oocyte quality and ovulatory function in women trying to conceive. The results of four key studies spanning over nine years are summarized below:

Study #1

Nutrients MI plus FA support oocyte quality.

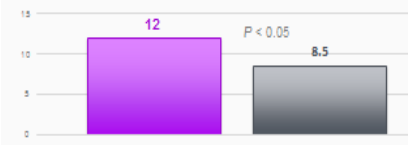
In a 2011 study, 34 patients were divided into two groups of 17. All of the women under the age of 40 were experiencing chronic anovulation, difficulties conceiving and were undergoing in vitro fertilization:

- Patients in Group A received 2000 mg of MI + 200 mcg of FA
- Patients in Group B received 200 micrograms of FA

Both groups received the nutrient intervention twice a day each day for three months.

At the end of the study, significantly more oocytes were retrieved from patients receiving the MI-FA supplement:

Median number of retrieved oocytes at the pick-up



Myo-Inositol + Folic Acid | Folic Acid Alone

Also, the number of follicles more than 15 mm in diameter, visible at ultrasound during stimulation, and the number of oocytes recovered at the time of pick-up were found to be significantly greater in the group treated with MI plus FA. Also significantly reduced was the average number of immature oocytes.

The authors conclude that the MI-FA combination may be useful in promoting oocyte maturation and improving oocyte quality.

Study: "Effects of myo-inositol supplementation on oocyte's quality in PCOS patients: a double-blind trial," L. Ciotta et al: *European Review for Medical and Pharmacological Sciences*, 2011 May;15(5):509-14.

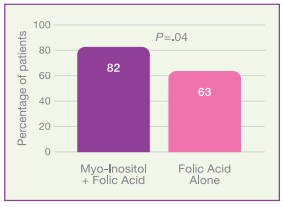
Study #2:
Nutrients MI plus FA support ovulatory function and menstrual cyclicity.

A total 92 women with irregular menstrual cycles were studied over 14 weeks:

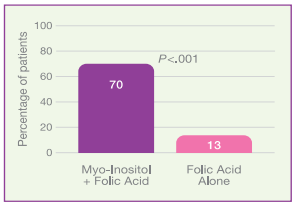
- 47 women received 400 micrograms of FA as a placebo
- 45 received 400 micrograms of FA *plus* 4 grams of MI

Compared with those who received folic acid alone, a significantly greater percentage of subjects receiving the MI-plus-FA supplement achieved:

Improved ovulatory function.



Normal ovarian rhythm (≥3 ovulations over 14 weeks).



The authors conclude that MI plus FA has a beneficial effect in improving ovarian function for women having difficulty conceiving.

Study: **"**Randomized, double-blind placebo-controlled trial: effects of myo-inositol on ovarian function and metabolic factors in women with PCOS," S. Gerli et al: *European Review for Medical and Pharmacological Sciences*, 2007 Sep-Oct;11(5):347-54.

Study #3

MI can support normal ovulatory function.

In a 2007 study using an observational design, 25 PCOS women of childbearing age with oligomenorrhea (infrequent or very light menstruation) were investigated following ingestion of MI and FA. The women were administered 2000mg of MI combined with 200mcg FA twice a day. During an observation period of six months, ovulatory activity was monitored with ultrasound scan and hormonal profile, and the number of spontaneous menstrual cycles and eventually pregnancies was assessed.

The study's authors hypothesized that administering MI would restore normal ovulatory function. The study found that:

- 22 out of the 25 patients (88%) had at least one spontaneous menstrual cycle during treatment.
- Of this group of 22, 18 (72%) continued ovulating normally.

The authors conclude that MI is a "simple and safe treatment that is capable of restoring spontaneous ovarian activity.

Study: **"**Myo-inositol in patients with polycystic ovary syndrome: a novel method for ovulation induction." Papaleo et al., *Gynecol Endocrinol.* 2007 Dec;23(12):700-3. Epub 2007 Oct 10.

Study #4

Higher concentrations of MI play a role in follicular maturity.

The goal of this prospective observational study was to determine whether the MI content in human follicular fluid (FF) was associated with better oocyte quality. The study looked at 53 patients treated with in vitro fertilization:

- Group A, 32 patients, was defined by patients having FF associated with matured and fertilized oocytes.
- Group B, 21 patients, was defined by patients having follicles with immature and unfertilized oocytes.

FF volume and its MI content were significantly higher in group A compared with group B. The levels of MI in FF were positively correlated with the amount of estradiol in their corresponding

FF samples and also correlated with embryo quality.

The authors conclude that higher concentrations of MI and estradiol in human FF appear to play a role in follicular maturity and provide a marker of good-quality oocytes.

Study: "Follicular fluid and serum concentration of myo-inositol in patients undergoing IVF: relationship with oocyte quality," Chiu et al.: *Human Reproduction*, 2002 17(8): 1591–1596.

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***The statements in this product briefing have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

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