

POLIGEN PLUS®

The polycystic ovary syndrome (PCOS) is one of the most common endocrinological troubles in fertile age women, is the most frequent cause of infertility linked to chronic anovulation (Lagana 2016). The recurrent miscarriage is more observed in women with PCOS. Furthermore, insulin-resistance (IR) associated to PCOS in more than 80% of obese patients is an important cause of non insulin-dependent diabetes.

Currently, many food supplements based on inositol or other substances that showed to be active in reducing the IR severity are available on the market.⁽¹⁾

New natural substances, have evidenced an insulin sensitizing action, that could be exploited to potentiate the clinical activity of a food supplement indicated for PCOS.

Among these ones, Cinnamon extract, is characterized by interesting properties in the treatment and prevention of insulin resistance, metabolic syndrome and diabetes mellitus type 2.

SOLUBLE TECHNOLOGY

Soluble formulations are solide immediate release forms that need to be dissolved in water with rapid stirring at the time of administration. They yield an oral solution or suspension depending on API solubility.

- **Fast onset of action**
- **Large amount of API**
- **High bioavailability**
- **Easy to manage than conventional liquids**
- **User friendly**
- **Solvent and alcohol free**

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POLIGEN PLUS®
FOOD SUPPLEMENT

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Food supplement for Polycystic Ovary Syndrome (PCOS) based on Myo-Inositol, D-chiro Inositol, Cinnamon extract, Chromium, Vitamin E and Folic Acid

Myo-inositol and D-Chiro inositol regulate insulin dependent processes. D-Chiro inositol (Caronositol[®]) is a natural inositol isomer extracted from the Carob tree which has shown a beneficial effect on the physiological balance in women with PCOS.⁽²⁾

Cinnamon extract is an herbaceous plant belonging to the Lauraceae family, is supported by most significant data of activity in PCOS. Cinnamon Increases Insulin Sensitivity and Glucose in PCOS and prevents the development of insulin resistance, at least in part by enhancing insulin signaling and possibly via the NO pathway in skeletal muscle. In polycystic ovary syndrome, metabolic syndrome, type 2 diabetes mellitus, cinnamon extracts show beneficial effects on glucose, insulin, insulin sensitivity, lipids, antioxidant status, blood pressure, lean body mass. Cinnamon has been shown to improve insulin resistance, elevated glucose and lipids, inflammation, decreased antioxidant activity, increased weight gain, and increased glycation of proteins, all variables associated with Metabolic syndrome.

Chromium is a very important oligoelement for regulating insulin secretion and contributes to maintenance of normal blood glucose levels.

Vitamin E has a marked anti-oxidant action, which protects human cells from oxidative stress.

Folic acid is often deficient in childbearing women with PCOS.

The combination of these substances in a unique formulation is very promising from pathophysiological point of view in controlling the disorder of PCOS and, particularly, Insuline Resistance.



CLINICAL DATA

Efficacy and safety of **POLIGEN PLUS[®]** have been under evaluation, preliminary, observational clinical study, in which women presenting troubles of the polycystic ovary syndrome, irregular cycles with anovulatory cycles, not so severe to require pharmacologic therapy, were recruited. The women included, aged between 18 and 30 years, underwent a clinical and echographical evaluation just after admission to the study (De Leo et al. 2017).

POLIGEN PLUS[®] is administered orally at the dose of 1 sachet/day for 4 week.

At baseline and after 4 weeks of treatment, the following exams are performed in all the women in early follicular phase of the spontaneous cycle and induced by a progestin:

- baseline blood sampling to determine fasting levels of glucose and insulin, and calculate HOMA index (glycaemia x insulinemia) / 22.5 where glycaemia is expressed in mmol/L and insulin in mU/L);
- Oral Glucose Tolerance Test (OGTT 75 g times 0, 30, 60, 90 and 120 min) to determine glycaemia and insulin in all samplings.
- acne and hirsutism evaluated by Ferriman-Gallwey score where 0=absent; 8-12=mild; 13-16=moderate; >16=marked (>16)
- regularity of menstrual cycle: number of menstruations in the previous 3 months (calculation of the expected cycles; in pretreatment, calculation is: no. of cycles in the last 12 months/12
- BMI evaluation
- total cholesterol and triglycerides

At the end of the treatment, the physician's overall judgement on the treatment and the woman's evaluation of the acceptability of the treatment are expressed by a semi quantitative scale where the score are: 0 = nil; 1 = poor; 2 = moderate; 3 = good; 4 = very good.

Phytosurveillance: any adverse reaction or unwanted event is recorded in the Case report form, specifying severity, duration, onset time, relationship with the treatment and the action taken.

INDICATIONS

POLIGEN PLUS[®] is a food supplement available in soluble granules (in sachet), useful for the wellness of women with PCOS and in case of increased need of those nutrients. It contributes to keep glucose-insulin metabolism in normal range and to regulate body weight. It favours a normal carbohydrate, lipid and protein metabolism.

HOW TO USE

1 sachet per day is recommended. The soluble granules should be dissolved in a glass of water.

- GLUTEN FREE
- LACTOSE FREE
- SUGAR FREE



INGREDIENTS

	Content for sachet/stick	% RNV*
MYO-INOSITOL	1000 mg	
D-CHIRO INOSITOL**	9 mg	
CINNAMON EXTRACT (<i>Cinnamomum verum</i> J. Presl., cortex, dry extract min. 20% proanthocyanidin)	1000 mg	
Vitamin E	36 mg	300%
Folic acid	400 µg	200%
Chromium	40 µg	100 %

(*) % Reference Nutrient Values - (**) Caronositol[®]

BIBLIOGRAPHY

⁽¹⁾ Laganà AS, Rossetti P, Buscema M, La Vignera S, Condorelli RA, Gullo G, Granese R, Triolo O. *Metabolism and Ovarian Function in PCOS Women: A Therapeutic Approach with Inositols*. Int JEndocrinol. 2016; 2016:6306410. Epub 2016 Aug 4.

⁽²⁾ Biosearch Life, Caronositol, www.biosearchlife.es/en/exxentia-2/caronositol/