



Genopause®

Role of the Ayurvedic formulation GENOPAUSE® on neuro-psycho-physiological assessments among menopausal women

A blend of ayurvedic plants for women

INTRODUCTION

The Climacteric and menopause processes are essentially related to the ovarian hormonal deficiency in mature women. The occurrence of menopause is not affected by socio-economic condition, race, height, weight, parity, etc. The primary causative deficiency that leads to the ovarian failure is the estrogen deficiency.

A variety of physiological, psychological and neuroendocrine changes attributed to menopause state because of estrogen deficiency. The classical symptom associated with estrogen deficiency are hot flushes, which is also described as a recurrent, transient period of flushing, sweating and a sensation of heat often accompanied by palpitation, feeling of anxiety and depression. Hot flushes during the menopause indicate a high level of oxidative stress and a higher cardiovascular risk.

The hormonal replacement therapy (HRT) may help significantly in maintaining bone mass and skeletal integrity, protects against cardiovascular diseases and decreases oxidative stress level. The hormone replacement therapy with estrogens and androgens provides greater improvement in psychological status like lack of concentration, depression and fatigue as well as an improvement of sexual function.

Nevertheless, there are certain health risks associated to HRT. Breast and endometrial cancers, gall bladder, thrombophlebitis and hypertension are the major risks that may manifest following HRT,

but it also includes vaginal bleeding, breast tenderness, mood changes, weight gain and water retentions.

The use of natural remedies can reduce the symptoms that many women experience during menopausal phase. If these remedies have no contraindications, they have a great potential for being extremely effective and safe options.

Ayurvedic remedies are based in the knowledge of the Ancient Ayurveda medicine. Some specific combination of Ayurvedic plants have shown, in many occasions, to be an effective natural approach to different illnesses and organic dysfunctions. Current Ayurveda practice combine the traditional knowledge of medicinal Indian plants with the most serious investigation based in clinical studies.

Keeping in mind the limitations of HRT, a proprietary Ayurvedic formulation was evaluated for its potential role in the management of neuro-psycho-physiological complaints associated with menopausal syndrome.

The Ayurvedic remedy, traded as GENOPAUSE®, contains a blend of the following Ayurvedic plant extracts: *Tinospora cordifolia*, *Asparagus racemosus*, *Withania somnifera* and *Commiphora mukul*.

The efficacy of GENOPAUSE® has been evaluated in two clinical studies showing efficacy to minimize the vasomotor instability, to regulate dyslipidemia, to prevent osteoporosis and to improve the associated psychological complaints in menopausal women.

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VERY IMPORTANT: To use the trademark and/or logo of the ingredient, **it is mandatory to sign a co-branding agreement**, as well as send the packaging design and the marketing material to be approved by the owner of the brand. The improper or unauthorized use of the brand or the non-compliance of the contract will conduct to the corresponding legal actions.

GENOPAUSE®: THE AYURVEDIC COMPOSITION

Tinospora cordifolia

The pharmacological activity of *Tinospora cordifolia* is related to the total bitter content, which can vary widely from region to region. Plant extracts cause reduction in fasting blood sugar and significantly inhibit epinephrine-induced hyperglycaemia. *Tinospora cordifolia* offers protection against a variety of biological-physical and chemical stressors.



Tinospora cordifolia

Asparagus racemosus

Asparagus racemosus it is a tall climbing shrub. The main active are sarsaponin and nine asparagosides isolated from roots. In India, the roots are used as sexual tonic. Like *Tinospora cordifolia*, *Asparagus racemosus* offers protection against a variety of biological, physical and chemical stressors.



Asparagus racemosus

Withania somnifera (Linn.)

Ashwagandha is characterized by the presence of steroidal lactones, withanolides, and alkaloids. The major alkaloid, withanine, possesses a marked sedative and hypnotic action. The plant present effects on central nervous system as well as smooth muscles.

Aswagandha is considered also as immunomodulatory and presents antidepressant activity bringing adaptogenic, cardioprotective and anti-coagulant properties.



Withania somnifera

Commiphora mukul

The gum resin of guggul contains essential oil with myrcene, dinercene and some polymyrcene. A number of different steroids have been also isolated from the gum of guggul. The oleoresin possesses a potent anti-inflammatory action as well as hypolipaemic activity.

The steroidal fraction decreases serum cholesterol level and, specifically guggulipid have been found to exhibit significant hypolipidemic activity. *Commiphora mukul* is also useful for the treatment of osteoarthritis of the knee.



Commiphora mukul

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CLINICAL RESULTS

The clinical studies made with GENOPAUSE® have demonstrated that the decline in psychological capabilities, which occurs because of the normal aging process, is arrested by the combination of the Ayurvedic plants present in GENOPAUSE® that may be used in the management of cognitive impairment and psychic involvements, including physiological disturbances associated with menopausal women.

The Ayurvedic composition of GENOPAUSE® is directly responsible of its efficacy.

In this sense, *Asparagus recemosus* offers protection against a variety of biological, physical and chemical stressors. Due to this property, the vasomotor and psychological symptoms are improved in menopausal women.

Tinospora cordifolia has been found to be beneficial in several studies. The anti-inflammatory, analgesic, hepatoprotective and anti-stress properties of this plant has been scientifically proven. It shows changes in norepinephrine, dopamine, 5-hydroxytryptamine and 5-hydroxyindoleacetic acid levels.

On the other hand, whitanolides contained in *Whitania somnifera* acts on brain producing tranquility and decreasing excitatory neurotransmitters. This is the reason why by improving nervousness, insomnia, anxiety, depression and mental performance the general health of post-menopausal women is also improved.

Finally, *Commiphora mukul* is used by its high potent anti-inflammatory action. In addition, guggulipid has significant hypolipidemic activity. Thus, the regulation of dyslipidemia reduces hypercholesterolemia, dyslipidemia and the risk of occurrence of coronary heart disease among the menopausal women associated to the estrogen deficiency.

The results obtained in the clinical studies indicates that GENOPAUSE® can be useful for the management of vasomotor complaint

and hot flushes but also preventing osteoporosis, reducing the possibility of bone fractures, and coronary heart attack among menopausal women.

SAFETY

In order to study the safety profile of each ingredient of GENOPAUSE® both, the acute and the chronic toxicity, were studied individually by using the plant extracts.

After determining the toxicity of each plant, the extract of all four plants were given simultaneously in different doses to decide the acute and chronic toxicity of GENOPAUSE® on experimental animal models.

The results showed a high index of safety, which makes GENOPAUSE® to be considered as safe for human consumption.

These results were confirmed by the fact that none of the women who participated in the two clinical studies showed any adverse reaction during the entire course of the studies.

Concerning the use of GENOPAUSE® in food supplements to point that all four plants are accepted to be used in Europe, as they are included in the Belgian Arrêtè Royal of 29 August 1997, updated on January 2017.

DOSAGE

Following the results of the clinical study, it is recommended to take 1 g of GENOPAUSE®, divided in two doses of 500 mg at day, at least for 6 months.

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