**Description**

**A COMPOSITION FOR THE TREATMENT OF ANDROPAUSE**

**Technical Field**

The invention relates to a composition formed for the use of low-dose isoflavones in the treatment of andropause.

**State of the Art**

For the treatment of andropause; the testosterone replacement therapy, DHEA therapy and growth hormone replacement therapy are currently employed. Testosterone therapy blocks the production of natural testosterone, suppresses the release of LH FSH, and causes the aromatase expression to increase and the externally administered testosterone to be converted to the estrogen derivatives.

Although the DHEA supplement yields very good results at low doses, since each individual has different endocrinal responses, the duration of use and the daily dose may not be adjusted very efficiently and the benign prostatic hyperplasia, elevated estrogen and thyroid imbalances may result in the medium term.

The growth hormone supplement, as in the intake of testosterone, causes the suppression of GHRH hormone that stimulates the production of the growth hormone and may, in case of overdose, exhibit undesirable side effects such as thyroid problems, carpal tunnel syndrome, heart enlargement and acromegalic symptoms.

As a result, the presence of the need for a composition formed for the use of low-dose isoflavones in the treatment of andropause and the inadequacy of the existing solutions have made it necessary to perform an improvement in the relevant art.

**Object of the Invention**

In order to eliminate the disadvantages of the state of the art, an object of the invention is to suppress the enzyme aromatase that enables the production of estrone and estradiol.

Another object of the invention is to suppress the production of the estrogen, like the aromatase-suppressing agents.

Another object of the invention is to stimulate the production of LH and FSH, reduce the level of SHBG and increase the production of free testosterone.

Another object of the invention is to increase the expression of 5-alpha-reductase in the cavernous tissue, thereby promoting the production of dihydrotestosterone.

Another object of the invention is to preserve the development of the male organs and the health of the prostate.

Another object of the invention is to prevent the hair loss effect of DHT owing to the functioning of the isoflavones like the estrogen hormone in the hair follicles, when elevated by way of isoflavonic stimulation.

Another object of the invention is to suppress the formation of corticosteroid and stimulate the DHEA release from zona reticularis, owing to the ability to suppress Src tyrosine kinase.

Another object of the invention is to provide somatotropic effect and stimulate the release of the growth hormone by binding to the GHRH receptors.

Another object of the invention is to prevent the blood sugar imbalances, carpal tunnel syndrome, acromegaly and possible carcinogenic cell mutations, owing to the ability to suppress SRC tyrosine kinase.

Another object of the invention is to reduce the levels of estrogen, cortisone and aldosterone and promote the development of the ideal endogenous hormone profile.

In order to achieve the aforesaid advantages, the invention is a composition for use in the treatment of andropause, said composition being obtained by the components selected from the group comprising 7-methoxypuerarin, methoxypuerarin, isopuerarin, isodaidzein, isogenistein that are used individually or in combinations.

The structural and characteristic features and all the advantages of the invention will become more clearly understood from the detailed description provided below and therefore, the evaluation must be made taking this detailed description into consideration.

**Detailed Description of the Invention**

The invention is a composition for the use of low-dose isoflavones in the treatment of andropause. Isoflavones are the components belonging to the family of flavonol glycosides naturally contained by many plant species. As tissue selectors, these components may exhibit anti-estrogenic and slight pro-estrogenic action in the body. In fact, they may treat the benign prostatic hyperplasia in the prostate tissue by way of simultaneous anti-estrogenic and slight estrogenic action.

The isoflavones, ingredients of the composition according to the invention, suppress the enzyme aromatase that provides the production of estrone and estradiol by interacting with androstendion and testosterone. When used cyclically at accurate dose and for accurate durations, the isoflavone formulations suppress the production of the estrogen, like the aromatase-suppressing agents, stimulate the production of LH and FSH, reduce the level of SHBG, increase the production of free testosterone and increase the expression of 5-alpha-reductase in the cavernous tissue, thereby promoting the production of dihydrotestosterone.

DHT (dihydrotestosterone) is an androgen derivative with about 10-fold stronger ability to stimulate the androgen receptor as compared to testosterone. This hormone preserves the development of the male organs and the health of the prostate. Although this hormone may cause the hair loss when elevated alone, the hair loss effect of DHT is prevented owing to the functioning of the isoflavones like the estrogen hormone in the hair follicles, when said hormone is elevated by way of isoflavonic stimulation. Isoflavones suppress the formation of corticosteroid and stimulate the DHEA release from zona reticularis, owing to the ability to suppress Src tyrosine kinase.

Methoxypuerarin and 7-methoxypuerarin have somatotropic effect and they stimulate the release of the growth hormone by binding to the GHRH receptors. Blood sugar imbalances, carpal tunnel syndrome, acromegaly and possible carcinogenic cell mutations likely to result from the elevated growth hormone level are prevented by the SRC tyrosine kinase suppressing ability of the isoflavone derivatives that provide this elevation. These components, being capable of simultaneously increasing the production of DHEA testosterone, DHT and growth hormone, also reduce the levels of estrogen, cortisone and aldosterone and promote the development of the ideal endogenous hormone profile.

The composition according to the invention contains 7-methoxypuerarin, methoxypuerarin, isopuerarin, isodaidzein, isogenistein.

Said formulation is obtained by a mixture of the aforesaid components according to the following ratios by weight:

5-12% 7-methoxypuerarin,

7-19% methoxypuerarin,

18-11% isopuerarin,

25-46% isodaidzein,

45-12% isogenistein.

The composition is obtained from the aforesaid components selected from the aforesaid group and used according to the mentioned weight ratio ranges individually or in combinations.

Said invention also encompasses the use of said composition for treating the andropause and the manufacture thereof for this purpose.

The composition according to the invention is used as follows:

Men at the age of 50-55, body weight 70-80 kg, 20 mg administered for 80 consecutive days, intervals of 12 days,

Men at the age of 50-55, body weight 80-100 kg, 35 mg administered for 40 consecutive days, intervals of 10 days,

Men at the age of 60-80, body weight 70-90 kg, 40 mg administered for 100 consecutive days, intervals of 6 days.

**CLAIMS**

1. A composition for use in the treatment of andropause, said composition being obtained by the components selected from the group comprising 7-methoxypuerarin, methoxypuerarin, isopuerarin, isodaidzein, isogenistein that are used individually or in combinations.
2. A composition according to Claim 1 characterized in that it comprises 5-12% by weight 7-methoxypuerarin.
3. A composition according to Claim 1 characterized in that it comprises 7-19% by weight methoxypuerarin.
4. A composition according to Claim 1 characterized in that it comprises 18-11% by weight isopuerarin.
5. A composition according to Claim 1 characterized in that it comprises 25-46% by weight isodaidzein.
6. A composition according to Claim 1 characterized in that it comprises 45-12% by weight isogenistein.
7. Use of the components according to Claims 1 to 6 obtained individually or in combinations from the group consisting of 7-methoxypuerarin, methoxypuerarin, isopuerarin, isodaidzein, isogenistein for the manufacture of a composition for treating the andropause.
8. Use of a composition according to Claim 7 characterized in that it is administered to men at the age of 50-55, body weight of 70-80 kg, at 20 mg for 80 consecutive days, with intervals of 12 days.
9. Use of a composition according to Claim 7 characterized in that it is administered to men at the age of 50-55, body weight 80-100 kg, at 35 mg for 40 consecutive days, with intervals of 10 days.
10. Use of a composition according to Claim 7 characterized in that it is administered to men at the age of 60-80, body weight 70-90 kg, at 40 mg for 100 consecutive days, with intervals of 6 days.

**ABSTRACT**

**A COMPOSITION FOR THE TREATMENT OF ANDROPAUSE**

The invention relates to a composition formed for use in the treatment of andropause.

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