**Description**

**FORMULATION INTENDED FOR TREATMENT OF HYPO-ADRENALISM**

**Field of Invention**

The present invention herewith is related to a formulation developed for treatment of hypo-adrenalism.

**Background of the Related Technology**

At present it is known that in mammalians the adrenal glands (also known as suprarenal glands) are endocrine glands that have a shape resembling a triangle. These glands take their name from their location, since anatomically they are just on top of the kidneys. These glands consist of two layers, called cortex (outer layer) and medulla (middle layer). Their basic function is, when under physiological stress, to secrete corticosteroids (from cortex) and to secrete cathecholamine (from medulla) into the blood stream.

Again, at present it is known that most of the irregularities related to the cortex layer of the adrenal glands is a result of synthesis of hormones at a certain layer, in a quantity higher or lower than the normally required levels (cortisol, aldosterone or sexual hormones). Having a certain hormone produced and secreted, at a level below or above the normal concentration, results in certain symptoms in a person and this also leads to variations in the concentration of the related hormone in the blood stream and urine. On the other hand, having a high or low level of a certain hormone, would have an impact on feedback mechanism of that hormone and certain analyses can be conducted solely based on this fact.

Based on the state of art technology in medicine, a total of 30 mg hydrocortisone is administrated per day in 2-3 doses, as a maintenance treatment. Two thirds of the required dose is given early in the morning and one third in the afternoon around 16:00 hr. By this method the circadian rhythm is mimicked. Administrating at a later hour can lead to certain side effects like sleep disorders. In primary adrenaline insufficiency treatment, mineralo-corticoid replacement treatment is required. Treatment is started with 0.1 mg/day dose of fludrocortisone (Florinef or Astonin) and the dose may be increased if needed. In certain studies, it is argued that, in women with primary adrenaline insufficiency, a treatment of 50 mg DHEA per day would regulate the life quality and mood of the women.

In state of art technology, invention no " EP2205562B1" , with title "1.1.1-trifluoro-2-hydroxy-3-phenylpropane Derivatives" and under classification number "C07D 213/30" discloses new 1,1,1 -trifluoro-2-hydroxy-3-phenylpropane or 1,1,1 -trifluoro-2-hydroxy-4-phenyl butane derivatives, manufacturing such agents as well as pharmaceutical compositions of these and using these as drugs. The active compounds that are in compliance with the invention act as glucocorticoid receptor modulators and preferably as antagonists and are useful in treatment of diabetes as well as other disorders like dyslipidemia, obesity, high blood pressure, cardio-vascular diseases, adrenalin imbalance or depression.

In state of art technology, invention no "WO 1999/045779" , with title " New Eprosartan Compositions" and under classification number " A01N 43/50" discloses a new composition containing eprosartan in particular form, or its salt, solvate or hydrate, as well as the method for manufacturing this composition. It also discloses the methods of using the composition in preventing new Angiotensin II receptors and in treatment of high blood pressure, congestive heart failure and kidney failure.

Again invention no " EP1274411B1" , with title "Using Phenylethylamines as Pro-drugs of Cathecholamines and Their Condensed Ring variants and Their Use” discloses compounds with general formula (I) and their salts containing pharmaceutically accepted acids or bases. It also discloses methods for manufacturing pharmaceutic compositions intended for treatment of Parkinson’s Disease, psychosis, Huntington’s Disease, impotency, renal failure, heart failure or high blood pressure, such pharmaceutical compositions intended for treatment of Parkinson’s Disease and Schizophrenia as well as methods related to such intensions.

Again invention no " EP1487424B1" , with title "4-(4-methylpiperazin-1-ylmethyl)-N-(4-methyl-3(4-piridin-3-yl)pirimidin-2-yl-amino)phenyl)-benzamid for Treatment of ANG II Induced Diseases” and under classification number "A61K 31/00" discloses methods for using a PDGF receptor tyrosine kinase inhibitor or a pharmaceutically appropriate salt of this for production of a drug for treatment of a disease induced by ANG II and its characteristic is to have it selected for the referred diseases induced by angiotensin II which includes; congestive heart failure, heart failure, cardiac hyperthrophy, cardiac remodeling after myocardial infarction, dilate or hyperthrophic cardiomyopathy related pulmonary congestion and cardiac fibrosis, prevention of stroke related to congestive heart failure, left and right ventricular hyperthrophy, hyperthrophic medial thickening of the arteries and/or large blood vessels, mesenteric vascular hypertrophy, renal hyperfiltration after portal renal ablation, proteinuria in chronic renal disease, renal arteriopathy as a result of high blood pressure, nephrosclerosis or hypertensive nephrosclerosis, mesangial hyperthrophy, endothelial dysfunctions exhibiting pro-inflammatory or pro-oxidant conditions.

To conclude it has become inevitable to proceed with a development in the area of the related technology, considering the inadequacy of the existing solutions and the need for a formulation intended for treatment of hypo-adrenalism

**Objective of the Invention**

To overcome the disadvantages experienced in state of art technology;

* One objective of the present invention is to enhance ACTH production;
* One other objective of the invention is to enhance CRH production;
* One other objective of the invention is to increase density and number of glucocorticosteroids;
* One other objective of the invention is to have the zona fasciculate cells to preserve their cell wall permeability.

The present invention which is aimed to achieve the above-mentioned advantages, is intended for treatment of hypo-adrenalism and is a formulation that is obtained by combination of the compositions selected in a single form or in combinations from a group containing; (3β,25R)-dispirost-5-ene-3-triol, 3,7-bis(2-hydroxymethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one, 3,5-bis(2-dimethoxyethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one.

Structural and characteristic properties as well as all the advantages of the invention presented herewith will be clearly understood with the detailed description provided below and thus the evaluation regarding the present invention should be based on the detailed description presented herewith..

**Detailed Description of the Invention**

The present invention is related to a formulation developed for treatment of hypo-adrenalism. Referred formulation enhances ACTH production, enhances CRH production, increases density and number of glucocorticosteroids, helps the zona fasciculate cells to preserve their cell wall permeability.

The formulation of the invention presented herewith contains; (3β,25R)-dispirost-5-ene-3-triol, 3,7-bis(2-hydroxymethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one, 3,5-bis(2-dimethoxyethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one .

The referred formulation is formed by mixing the above-mentioned components at below percentages by weight;

* 26-44% of (3β,25R)-dispirost-5-ene-3-triol,
* 54-28% of 3,7-bis(2-hydroxymethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one,
* 20-28% of 3,5-bis(2-dimethoxyethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one.

Components given above are obtained by combining the components from the above-mentioned group at the given range of weight ratios in a single form or in combinations thereof.

The present invention at the same time is related to using the above-referred formulation for treatment of hypo-adrenalism and manufacturing it for such purpose.

**CLAIMS**

1. A formulation intended for treatment of hypo-adrenalism, which consists of combining the components selected from the group; (3β,25R)-dispirost-5-ene-3-triol, 3,7-bis(2-hydroxymethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzo pyrane-4-one, 3,5-bis(2-dimethoxyethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one in a single form or in combinations thereof.
2. The formulation of Claim 1 which is characterized by containing 26-44% of (3β,25R)-dispirost-5-ene-3-triol by weight.
3. The formulation of Claim 1 which is characterized by containing 54-28% of 3,7-bis(2-hydroxymethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one by weight.
4. The formulation of Claim 1 which is characterized by containing 20-28% of 3,5-bis(2-dimethoxyethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one by weight.
5. Using the compositions obtained by selecting singly or in combination of components from the group of; (3β,25R)-dispirost-5-ene-3-triol, 3,7-bis(2-hydroxymethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one, 3,5-bis(2-dimethoxyethyl)-8-(3-methyl-2-butene-1-yl)-4H-1-benzopyrane-4-one from any one as given in Claims 2-4 in manufacturing the formulation intended for treatment of hypo-adrenalism.

**SUMMARY**

**FORMULATION INTENDED FOR TREATMENT OF HYPO-ADRENALISM**

The present invention is related to a formulation developed for treatment of hypo-adrenalism. Referred formulation enhances ACTH production, enhances CRH production, increases density and number of glucocorticosteroids, helps the zona fasciculate cells to preserve their cell wall permeability.

There are no illustrations.