

30 Tablets
257.05
mg

ESTROGEN FREE SOLUTION

FORMIS

Cynanchum wilfordii, *Phlomis umbrosa*, *Angelica gigas*

Nutraceutical Product

SUPPLEMENT FACTS

Each film coated tablet contains

Cynanchum wilfordii.....83.54mg

Phlomis Umbrosa.....83.54mg

Angelica gigas.....89.97mg

(PharmEvo Specs.)

DESCRIPTION

FORMIS is made from 3 botanical extracts i.e. *Cynanchum wilfordii*, *Phlomis umbrosa* and *Angelica gigas*. It has been suggested as an alternative to hormone replacement therapy (HRT) for treating post-menopausal symptoms in women such as hot flashes, night sweats, paresthesia, insomnia, nervousness, melancholia, vertigo, fatigue, rheumatic pain, vaginal dryness and other symptoms of female sexual dysfunction.

Hormone replacement therapy (HRT) consists of several prescription drugs for treating menopausal symptoms; however, these agents have exhibited side effects including the risk of estrogen-induced breast cancer. FORMIS is suggested as an herbal alternative containing 3 botanical extracts that improve menopausal symptoms without inducing estrogenic activity and potential risk of breast cancer.

In several studies herbal combination of *Cynanchum wilfordii*, *Phlomis umbrosa* and *Angelica gigas* has been shown to lack of affinity for both alpha- and beta-estrogen receptors in vitro, thus confirming the non-estrogenic mode of action. It does not show estrogenic activity or stimulate promoters containing estrogen response elements in MCF-7 cell lines. It shows no significant selective activity against hER α and hER β , non-selective activity against the ER (estrogen) receptors, or effects on ER (estrogen) target gene expression.

PHARMACOLOGICAL PROPERTIES

MECHANISM OF ACTION

The mechanism of action has not been fully elucidated. The substantial menopausal relief due to *Cynanchum wilfordii*, *Phlomis umbrosa* and *Angelica gigas* may stem from the ability to provide activity that is similar to the action of the drug class known as selective estrogen receptor modulators, or SERMs. These are the agents that unlike distinct estrogen agonists or estrogen antagonists, (which either boost or block estrogen); selectively enhance estrogenic activity in some tissues while inhibiting estrogenic activity in other tissues. In this way, FORMIS may work by mimicking the benefits of SERM drugs without influencing the levels of estradiol (E2) and follicle stimulating hormone (FSH) and potential health risks of HRT drugs.

PHARMACOKINETICS

The ADME of the combination product or its individual components i.e. *Cynanchum wilfordii*, *Phlomis umbrosa* and *Angelica gigas* have not been established.

THERAPEUTIC USES

FORMIS is recommended for the treatment of post-menopausal symptoms in women.

- Hot flashes
- Vaginal dryness
- Tingling
- Nervousness
- Melancholia
- Dizziness
- Fatigue
- Rheumatic pain
- Insomnia
- Paresthesia

Clinical Evidence:

The efficacy and safety of the herbal actives contained in FORMIS have been demonstrated in several RCTs.

The positive data obtained from the 1-year clinical study with 48 South Korean women revealed that the formulation significantly ameliorated various menopausal symptoms and did not show any elevations of body weight, body mass index (BMI), and serum levels of Estradiol (E2) and Follicle Stimulating Hormone (FSH).

Another randomized, double-blinded, placebo-controlled clinical study performed in 64 women for 12 weeks showed a significant improvement in various menopausal symptoms such as hot flashes and night sweats, paresthesia, insomnia, nervousness, melancholia, vertigo, fatigue, rheumatic pain, and vaginal dryness compared to placebo group. Furthermore, no significant changes were observed in body weight, BMI, serum estradiol (E2) and FSH levels, and liver enzymes that show elevations following treatment with conventional HRT drugs. The herbal combination of *Cynanchum wilfordii*, *Phlomis umbrosa* and *Angelica gigas* reduced Kupperman Menopausal Index score (a measure of menopausal symptoms) by 62% in the treatment group, contrasted with a decrease of just 19% in the placebo group.

DOSAGE AND ADMINISTRATION

One tablet twice a day orally. Suggested duration of therapy is 12 weeks.

CONTRAINDICATIONS

None established.

WARNINGS AND PRECAUTIONS

None established

ADVERSE REACTIONS

None reported

DRUG INTERACTIONS

None reported

USE IN SPECIAL POPULATIONS

Pregnancy and Nursing mothers

Safety and efficacy of the formulation or individual constituents have not been established in pregnant women and lactating mothers.

Renal impairment

No data available

Hepatic impairment

No data available

OVERDOSAGE

No data available with regards to over dosage of the formulation or its individual ingredients

PRESENTATION

FORMIS: Pack of 30 tablets

INSTRUCTIONS

Use as advised by the physician.

Keep out of the reach of children.

To be sold on the prescription of a registered medical practitioner only.

Protect from heat, light and moisture.

Store below 30°C.

For suspected adverse drug reaction, report at

pharmacovigilance@pharmevo.biz

For more information on our products

call PharmAssist helpline 0800-82222

Monday to Friday 9:00 am to 6:00 pm

or email us at: pharmassist@pharmevo.biz

Manufactured by:



Our dream, a healthier society

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