

Gonadil-f®

(Tribulus terrestris Ext. Comp.)

PRODUCT DESCRIPTION

Gonadil-F is an innovative combination of non-hormonal, highly effective and safe natural compounds. **Gonadil-F** also contains specific ingredients in an appropriate therapeutic dose, which ensures the enhancement of male sexual vigour and vitality.

Gonadil-F is a unique formulation of the natural extract of *Tribulus terrestris*, a highly effective and safe compound, widely used by millions of people for successful treatment of a wide range of male sexual health disorders. In addition to high quality, standardized, natural active substance *Tribulus terrestris*, **Gonadil-F** contains premium quality important nutritional ingredients such as **L-Opti Zinc**, **Vitamin E** and **Selenium** in an appropriate therapeutic dose. Thus **Gonadil-F** is appropriate for effective and safe treatment of common sexual male health problems with many additional health benefits.

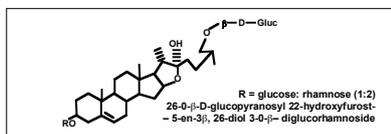
QUALITATIVE AND QUANTITATIVE COMPOSITION

Gonadil-F is available for oral administration as:

Each capsule of **Gonadil-F** contains:
Tribulus terrestris Extract ... 250mg-300mg
L-Opti Zinc
Vitamin E
Selenium

ACTIVE SUBSTANCE CONTENTS-TRIBULUS TERRESTRIS

Tribulus terrestris extract compound is a non-hormonal complex. Its active components are saponins of furastanol type, standardized on the basis of predominating compound, protodioscine. The structural formula of protodioscine is (2:1), 26-O-beta-1-glucopyranosyl, 22-hydroxyfurost-5-en-3-beta, 26-diol, 3-O-beta-diglucoammonide.



PROPERTIES OF THE PREPARATION

Pharmacological Effects, Mode of Action

Tribulus terrestris

Tribulus terrestris enhances endogenous testosterone levels through the increase in luteinizing hormone (LH), a gonad stimulating hormone produced by the anterior pituitary gland.

Tribulus terrestris in recommended dose leads to elevate testosterone levels within approximately 60 minutes after dosing.

Tribulus terrestris peak levels are achieved in 3 to 4 hours post dosing. Clinical studies have shown that Tribulus terrestris increases endogenous testosterone production levels by 30% or more in five days.

Tribulus terrestris improves the spermatogenesis and increases the number of spermatogonia, spermatocytes and spermatozoa in the testes without producing any effect on the diameter of seminiferous tubules. Regular use of Tribulus terrestris results in an intensification of spermatogenesis, improves the sperm quality. It enhances the sperm motility and percentage of actively mobile spermatozoa and prolongs sperm viability.

Hypothesis of the central effect of Tribulus is lead by the elevated LH levels. It may produce its effects by being metabolized into androgen-like metabolites or stimulating the physiological transformation of testosterone into dehydrotestosterone (DHT). Tribulus terrestris may exert a direct action on the hypothalamus and other superior brain structures that regulate the gonadotrophic releasing factors.

An important feature of pharmacodynamics of Tribulus terrestris is the regulation of body's hormonal balance without any interference with its functional mechanism.

PHARMACOKINETICS

Absorption, Distribution, Metabolism & Elimination

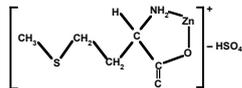
The active substance protodioscine is shown to be rapidly eliminated from the plasma, since its concentration is almost insignificant after 180 minutes. The clinical test revealed that the 24 hours excretion of the active substances show that 12%-14% of the compound is being excreted with bile, whereas urinary excretion is about 6%-7% for 50mg- 200mg/kg body mass as single intravenous dose administration. Following oral administration of similar doses, quantity of protodioscine being excreted through bile ranges from 2%-5% in 24 hours. Following the oral administration, no measurable concentration of any unaltered protodioscine was found in urine after 24 hours.

The experimental studies suggest that the hepatic route is the preferred route of excretion of unchanged protodioscine. The rapid elimination of protodioscine, the active content of Tribulus terrestris and the lower percentage of unchanged protodioscine in relation to the doses reveals the intensive biotransformation of protodioscine within the body.

ACTIVE SUBSTANCE CONTENTS - L-Opti Zinc

L-Opti Zinc is Zinc monomethionine, a premium quality nutrient that combines the essential trace mineral Zinc with the amino acid methionine and an acid sulfate anion in a 1:1:1 ratio.

Molecular structure of zinc monomethionine



In this well-defined organic chemical entity, the zinc ion is coordinated with the amino and carboxyl groups of the amino acid methionine. The remaining vacant bonds in the coordination sphere of zinc are occupied by the acid sulfate anion (HSO₄⁻) and water molecules. L-Opti Zinc is FDA certified, approved and safe for human use. L-Opti Zinc is better than ordinary zinc supplements and its bioavailability is 100% more than ordinary zinc. Due to special molecular combination of methionine, L-Opti Zinc delivers superior antioxidant protection.

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L-Opti Zinc developed by Inter Health USA, is covered by three patents. L-Opti Zinc is highly soluble, readily bioavailable and its purity as 100% organically bound zinc in a well-defined stable complex that provides consistent results.

The amino acid, methionine, is essential for the absorption, transportation and bioavailability of selenium. Combined with vitamin E, selenium has synergistic effects in the treatment of heart disease, cardiac muscles and tissue damage due to restricted blood flow.

PROPERTIES OF THE PREPARATION

Role of Zinc in the Human Body: Zinc is essential for normal growth, reproduction, digestion, respiration, as well as brain, nerve, vision, immune function and body maintenance. Zinc is a constituent of more than 200 enzymes involved in most major metabolic pathways that form the very basis of life. Zinc is found in every tissue and tissue fluid in the body.

Zinc plays a key role in the synthesis and stabilization of genetic material, necessary for cell division, synthesis and degradation of carbohydrates, lipids and proteins and is therefore essential for the growth and repair of tissue.

The highest concentrations of zinc are in the prostate gland and sperm in men. It is vital for male sex hormones and prostate function. Semen contains high concentrations of zinc and it plays an important role in sperm maturation and fertility regulation.

Zinc is also a very potent antioxidant and fights free radicals in multiple ways. As part of the enzyme copper-zinc superoxide dismutase, zinc helps to protect cells and other compounds against the effects of free radicals.

Zinc is vital for the normal structure and function of cell membranes, formation of connective tissue, teeth, bone, nails, hair and skin. Zinc also plays a role in calcium uptake in bone and modulates the effects of growth hormones.

Zinc is necessary for the secretion, synthesis and utilization of insulin. It also protects the insulin producing pancreatic beta cells against destruction. Population studies suggest that low blood zinc levels are associated with increased risk of cardiovascular diseases. Zinc protects the inner lining of blood vessels from damage, thus helping to prevent atherosclerosis.

A lack of zinc can reduce testosterone levels. For men with low testosterone levels zinc supplementation raises testosterone levels and also increases fertility. For men with low semen zinc levels, zinc supplements for at least several months may increase both sperm counts and fertility.

Excretion of zinc is mainly via the feces but some is lost in the urine. Excessive sweating can cause losses of up to 3mg per day. Zinc is not well stored in the body and a reduction in dietary intake leads to deficiency fairly quickly. Plasma or serum zinc levels may not reflect total zinc levels in the body, rather white blood cell measures of zinc may be the most accurate way to assess body stores.

ACTIVE SUBSTANCE CONTENTS -Vitamin E

PROPERTIES OF THE PREPARATION

Role of Vitamin E in the Human Body: Vitamin E formerly labeled "anti-sterility" vitamin and it is essential to regulate reproductive function in both men and women. Vitamin E, being one of the body's main antioxidant nutrients, protects hormones from oxidation. Clinical research and experience suggest that supplementation with 400IU-800IU of vitamin E may improve fertility in men.

Vitamin E is incorporated into the lipid portion of cell membranes and carrier molecules and protects these structures from toxic compounds, heavy metals, drugs, radiation and free radicals.

Vitamin E also protects cholesterol from oxidative damage. As a powerful antioxidant, vitamin E protects cell membranes and other fat-soluble parts of the body. The published studies revealed that regular intake of 400IU-800IU per day of vitamin E made a significant drop in the risk of heart disease.

It is important to note that a diet high in unsaturated fat increase vitamin E requirements & vitamin E works together with Selenium to protect fat-soluble parts of the body.

The most commonly recommended dose of vitamin E for adults is 400IU- 800IU per day. Vitamin E toxicity is very rare. In studies where benefits of vitamin E supplementation have been shown, the doses used (daily doses of up to 536mg/800IU or even 804mg/1200IU), have usually well exceeded the RDA's.

Vitamin E is essential for the maintenance of a healthy immune system, it protects the thymus gland and circulating white blood cells from damage, particularly during oxidative stress and viral illness. Vitamin E is vital for healthy eyes. As an antioxidant, vitamin E protects against the effect of aging by destroying free radicals, which cause degeneration in tissues such as skin, blood vessels. Vitamin E may also protect against various cancers and the mental effects of aging, such as memory loss.

Regarding the daily intake, almost all vitamin E research shows that positive results require hundreds of units per day an amount impossible with food but easily obtained by supplements.

ACTIVE SUBSTANCE CONTENTS - Selenium

PROPERTIES OF THE PREPARATION

Role of Selenium in Human Body: Selenium is an essential trace element and a powerful antioxidant, 50-100 times more potent than vitamin E. It works best when taken with vitamin E. Selenium plays a vital role in maintaining normal liver function, protein synthesis, healthy heart and protecting against toxic minerals. It plays a vital role in promoting male sexual reproductive capacity and helps to regulate male hormones, supports prostate function. Evidence suggests that in males, maintaining adequate levels of selenium may reduce the risk of prostate cancer, since it has been reported that males with prostate cancer have significantly lower levels of selenium. Recent studies found that men exposed to most dietary selenium developed 65% less advanced prostate cancer than men with lowest levels of selenium. A deficiency of selenium may contribute to affect the efficiency of vitamin E. Selenium is a very vital antioxidant especially when combined with vitamin E. It protects the immune system by preventing the formation of free radicals. Selenium acts synergistically with vitamin E to aid in the production of antibodies and to maintain a healthy heart. It is also important for pancreatic normal function and tissue elasticity and also needed to activate thyroid hormones.

Selenium as part, activates the, enzyme glutathione peroxidase, which may help to protect the body from cancer.

Organic selenium, such as that found in yeast, is more efficiently absorbed than inorganic salts. The average adult body contains about 20mg of selenium and most of this is concentrated in the kidneys, liver, heart, spleen and testes.

Selenium supplements may be beneficial in the treatment of rheumatoid arthritis, especially when combined with vitamin E. It also protects eyes from cataracts and reduces cancer risk. Selenium is important in maintaining resistance to diseases, enhancing the production and effectiveness of white blood cells and protecting them from the free radicals they generate in the process of fighting infection. Selenium also increases the antibody production and strengthens the body's surveillance of abnormal cell growth.

Large doses of vitamin C can interfere with the absorption and use of inorganic selenium, therefore, should not be mixed with vitamin C and should be taken at least 30 minutes apart.

INDICATIONS

Gonadii-F capsules are effective and safe for the treatment of following indications, when used regularly according to the recommended dosage and duration.

- ♣ Male sexual health problems related to performance, like
 - ♣ Low sex drive
 - ♣ Decreased libido
 - ♣ Premature ejaculation
 - ♣ Impotence
 - ♣ Weak erection or difficulty to maintain erection
 - ♣ Sexual asthenia/weakness/decreased stamina
 - ♣ Low sex drive due to stress, overwork, fatigue, mental tension
 - ♣ Decreased libido due to aging
 - ♣ Andropause or aging effects on sexual behavior
 - ♣ General male health vitality
- ♣ Male infertility disorders due to
 - ♣ Oligospermia
 - ♣ Oligoasthenospermia
 - ♣ Hypogonadotropic Hypogonadism
 - ♣ Hypogonadism
 - ♣ LH / Testosterone Deficiency Disorders

DOSAGE & ADMINISTRATION

Unless otherwise advised by the doctor recommended dosage of **Gonadii-F** is 1-2 capsules once or twice daily with meals for at least 4-12 weeks. The dosage and duration of treatment may be adjusted according to the characteristics and severity of problem.

For better and effective results **Gonadii-F** capsules must be used regularly without missing a dose. After completion of the recommended duration, a maintenance therapy at a dose of 1-2 capsules per day for another 2-4 weeks must be followed for better compliance. Prolonged use of **Gonadii-F** does not cause any harmful side effects.

In cases of male infertility due to oligospermia, **Gonadii-F** should be regularly used for at least 12 weeks or more. To confirm the improvement in sperm count and motility a sperm / semen test should be followed after completion of course since normal sperm takes 72 days to become mature and motile. In such patients the therapy should be continued till the time his spouse achieves conception.

For males who are smokers, over worked, overstressed or have crossed 35 years of age, the maintenance therapy may be extended to longer periods for better results and improved quality of sexual health and endurance.

In case the patient is a diabetic, prolonged duration of maintenance therapy would be beneficial to maintain better health and well being and significant improvement in daily life and work performance.

CONTRAINDICATIONS

Gonadii-F is contraindicated in patients with possible or known hypersensitivity to any of its ingredients.

ADVERSE DRUG REACTIONS

None have been observed so far. Clinical trials and experience have reported a very good tolerance and an absence of any adverse reaction related to Tribulus terrestris.

DRUG INTERACTIONS OF CLINICAL IMPORTANCE

The combination of **Gonadii-F** with gonadotropic hormones may result in a mutual potentiation of the effects of Tribulus terrestris.

SPECIAL INSTRUCTIONS

To achieve desired therapeutic results, it is important to follow the recommended dosage and duration of treatment or as advised by the doctor. Regular use of **Gonadii-F** without missing a dose should be considered important. Irregular or interrupted use can lead to decreased treatment success and failure to achieve the desired results. It is important to follow the recommended treatment duration with a maintenance therapy of 1-2 capsules daily with meals for another period of 2-4 weeks. This duration can be extended for individual patients, if desired, without fear of any harmful side effects.

OVERDOSE

Special attention has been paid to the evidence about the safety of the preparation. Under experimental conditions, no evidence of any acute, sub-chronic and/or chronic toxicity (behavioral, hematological, functional, biochemical and/or morphological investigations) have been established whatsoever. There is no evidence of any carcinogenic, teratogenic and/or embryotoxic effect either.

The experiments showed no toxic effect of Tribulus terrestris upon the animals. LD₅₀ toxicity for intra peritoneal administration is 750mg / kg body mass, whereas for oral administration is more than 10,000mg/kg body mass and no symptoms of overdose and or toxicity have been observed during the clinical trials.

STORAGE CONDITIONS

Store below 30°C. Protect from sunlight and moisture.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

Gonadii-F capsules are available in blister pack of 4 x 10's.

Keep out of reach of children.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:

 **Getz**
pharma
(PVT) LIMITED | 29-30/27,
K.I.A., Karachi,
Pakistan
www.getzpharma.com

L01-200007147