ZADE VITAL PUNIMIN

ZADE VITAL PUNIMIN 400 MG SOFT GELATIN CAPSULES 1. NAME OF THE MEDICINAL PRODUCT FOR HUMAN USE: *ZADE VITAL PUNIMIN 400 mg soft gelatin capsules* ***2. QUALITATIVE AND QUANTITATIVE COMPOSITION Active ingredient:*** *Each soft gelatin capsule contains 400 mg of pomegranate (Punicagranatum) seed oil as active ingredient. Excipients: 0.0805* g of glycerine. For the full list of excipients, see section 6.1. ***3. PHARMACEUTICAL FORM:*** *Soft gelatin capsules. Yellowish, oblong soft gelatin capsules* ***4. CLINICAL PARTICULARS: 4.1.*** **Therapeutic indications:** *ZADE VITAL PUNIMIN is used to protect health as an immune system booster due to its antioxidant activity, and also to help lower levels of blood lipids known* as triglycerides. ***4.2. Posology and Method of administration Posology/frequency and duration of administration:*** *Unless otherwise recommended by the physician, the dose of ZADE* VITAL PUNIMIN 400 mg soft gelatin capsules for adults is 1 to 2 capsules per day (at a dose of 400 to 800 mg/day). Method of administration: Capsules should be swallowed with a sufficient amount of water and preferably on a full stomach and not be chewed or crushed. Additional information concerning special populations: Renal/hepatic failure: Since no adequate safety studies have been performed in patients with renal and hepatic failure, it should not be used in these groups of patients. Paediatric population: Since no adequate safety studies have been performed in this population, it should not be used in those under 12 years of age. Geriatric population: No adequate safety studies have been performed in this population. ***4.3.*** **Contraindications:** *It should not be used in those who are allergic to the active substance or any other ingredient of ZADE VITAL PUNIMIN, during pregnancy and lactation, and in patients* with hepatic and renal failure. ***4.4. Special warnings and precautions for use:*** *ZADE VITAL PUNIMIN contains glycerine. It requires no warning due to its amount. It is recommended that the use of ZADE VITAL PUNIMIN for more than 2 months should be consulted with a physician.* ***4.5. Interaction with other medicinal products and other forms of interaction:*** *The* daily dose of ZADE VITAL PUNIMIN should not exceed 3 g/day in patients taking oral anticoagulants. Additional information concerning special populations: No interaction studies have been performed regarding special populations. Paediatric population: No interaction studies have been performed regarding the paediatric population. ***4.6. Pregnancy and lactation*** **General recommendation:** *Pregnancy Category: C. Women of childbearing potential/Contraception: Since no studies have been performed regarding this issue, it should not be used.* Pregnancy: Since no studies have been performed regarding the use of pomegranate (Punicagranatum) seed oil during pregnancy, it should not be used Lactation period: Since no studies have been performed for this group of patients, it should not be used. Fertility: Since there are no adequate safety data, it should not be used. ***4.7. Effects on ability to drive and use*** **machines:** *No studies have been performed regarding its effect on the ability to drive and use machines.* ***4.8. Undesirable effects:*** *The following terms and frequencies are used: Very* common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (cannot be estimated from the available data). Gastrointestinal diseases: Unknown: Nausea, vomiting, diarrhoea. No undesirable effects other than these have been reported so far. ***4.9. Overdose and Treatment:*** *No overdose* of pomegranate (Punicagranatum) seed oil has been reported so far. In case of overdose, the treatment should be ceased and a physician should be consulted. ***5. PHARMACOLOGICAL*** **PROPERTIES 5.1 Pharmacodynamic properties:** *The pharmacotherapeutic group (ATC code) has not been identified yet. Punicic acid that is the main component of pomegranate seed oil* is demonstrated to have effects to prevent lipid peroxidation in vitro and in vivo. It shows an antioxidative effect by inhibiting hydroperoxidation. It blocks inflammatory cytokines, increases insulin sensitivity, and boosts the immune system. In vitro and in vivo studies demonstrate that punicic acid that is a conjugated fatty acid and the main component of pomegranate seed oil has antiatherogenic effects. In the studies, it is aimed at identifying the effects of the treatment with pomegranate seed oil on serum lipid profiles. 51 hyperlipidemic patients have been taken into a randomised, double-blind, placebo-controlled clinical trial, and diagnosed according to the definition of the National Cholesterol Education Program, and randomly assigned to the pomegranate seed oil and control groups. The pomegranate seed oil and placebo groups have taken 400 mg of pomegranate seed oil and placebo two times a day respectively and have been followed up for 4 weeks. The serum concentrations of fats and fat proteins have been measured before starting the study and 4 weeks after starting the study. It is observed as a result of comparing the pomegranate seed oil group with the basal values at the end of 4 weeks that the TAG and TAG: HDL cholesterol (HDL-C) ratio has substantially decreased. Pomegranate seed oil is demonstrated to contain phytoestrogenic compounds (17-alpha-estradiol, estrone, estradiol and testosterone). It is known that these compounds are used to help remedy menopausal symptoms experienced during menopause due to their weak estrogenic effects (sleep disorders, hot flush, night sweats, etc.). It is reported that pomegranate seed oil capsules taken by humans 2 times a day for 12 weeks have remedied sleep disorders in menopausal women. Also it is reported that pomegranate seed compounds have increased bone density in mice with ovariectomy and reduced depressive symptoms during menopause. In the clinical trials conducted in patients with type-II diabetes, it is demonstrated although pomegranate seed oil has not reduced the insulin levels in a statistically significant way, it has significantly decreased the serum C peptide level. This gives rise to the thought that pomegranate seed oil increases insulin sensitivity. It is reported that the administration of pomegranate seed oil for 12 weeks has reduced the diet-induced weight gain, obesity, insulin resistance and risk of developing type-2 diabetes in mice. It is indicated that also in the experimental diabetes models created in Zucker rats using streptozotocin and alloxan, the compounds derived from various fractions of pomegranate positively affect the diabetes parameters. ***5.2. Pharmacokinetic properties General Properties:*** *There are no adequate dataregarding the absorption, dispersion, metabolism and elimination of pomegranate (Punicagranatum) seed oil.* ***6. PHARMACEUTICAL PARTICULARS 6.1. List of excipients:*** *d-l α-tokoferol, d-l α-tocopheryl acetate, Gelatin, Glycerine, Pure water.* ***6.2. Incompatibilities:*** *There are not any known incompatibilities.* ***6.3. Shelf life:*** *24 months.* ***6.4. Special precautions for storage:*** *Store at room temperature below 25°C.* ***6.5. Nature and contents of packaging:*** *It is available in PVC/Al blister packs containing 60 capsules together with the package leaflet in boxes.* ***7. MARKETING AUTHORISATION HOLDER:*** *Helvacızade Gıda İlaç Kimya San ve Tic. A.Ş. Address: Fevzi Çakmak Mah. Ankara Yolu üzeri 6.Km. 42050 Karatay/KONYA/TURKEY Telephone:+90 (332) 346 05 20 Fax: +90 (332) 346 05 29 E-mail: zade@zade.com.tr* ***8. MARKETING AUTHORISATION NUMBER:*** *2016/829* ***9. DATE OF FIRST AUTHORISATION OR RENEWAL OF THE AUTHORISATION Date of first authorisation:*** *21.11.2016*