ZADE VITAL CUCURMIN

ZADE VITAL CUCURMIN 320 MG SOFT GELATIN CAPSULES 1. NAME OF THE PRODUCT: *ZADE VITAL CUCURMIN 320 mg soft gelatin capsules* ***2. QUALITATIVE AND QUANTITATIVE COMPOSITION Active ingredient:*** *Each soft gelatin capsule contains 320 mg of pumpkin (Cucurbitapepo L.) seed oil (OleumCucurbitae semen). Excipients: 0.0805 g of glycerine. For excipients, see 6.1.* ***3. PHARMACEUTICAL FORM:*** *Soft gelatin capsules. Yellowish, oblong soft gelatin capsules* ***4. CLINICAL PARTICULARS 4.1. Therapeutic indications:*** *ZADE VITAL CUCURMIN is rich in essential fatty acids. It is used to help treat lower urinary system symptoms related to BPH (Benign Prostatic Hyperplasia), overactive bladder and urinary incontinence.* ***4.2. Posology and method of administration Posology/frequency and duration of administration:*** *Unless otherwise recommended by the physician, the dose of ZADE VITAL CUCURMIN* for adults is 1 to 3 capsules 3 times a day (at a dose of 960 to 2880 mg/day) taken orally. 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: ZADE VITAL CUCURMIN should be used in children under 18 *years of age and adolescents under supervision of a physician. Geriatric population: No studies have been performed in elderly patients.* ***4.3. Contraindications:*** *It should not be used in* those who are allergic to the active substance or any ingredient of ZADE VITAL CUCURMIN, during pregnancy and lactation, and in patients with hepatic and renal failure. ***4.4. Special* warnings and precautions for use:** *The daily dose of ZADE VITAL CUCURMIN should not exceed 3 g in patients taking oral anticoagulants. Each ZADE VITAL CUCURMIN capsule contains* 0.0805 g of glycerine. However, no adverse effect related to such dose of glycerine is expected. If your complaints worsen or symptoms such as fever, spasm, haematuria, dysuria or urinary retention are observed during the use of ZADE VITAL CUCURMIN, consult your physician or pharmacist. It is recommended that the use of ZADE VITAL CUCURMIN for more than 2 months should be consulted with a physician. ***4.5. Interaction with other medicinal products and other forms of interaction:*** *No interaction studies have been performed with other drugs or* medicinal products. The daily dose of ZADE VITAL CUCURMIN should not exceed 3 g 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 Women of childbearing potential/Contraception Pregnancy:** *There are no clinical data regarding the exposure to pumpkin seed oil* during pregnancy. The studies conducted in animals are not adequate for the effects on pregnancy and/or embryonic/fetal development and/or birth and/or post-birth development. The potential risk for humans is unknown. There are no adequate data regarding its use together with oral contraceptives. Since its safety in pregnancy is not proven, the use of ZADE VITAL CUCURMIN during pregnancy is not recommended. Lactation period: Since its safety in lactation is not proven, the use of ZADE VITAL CUCURMIN during lactation is not recommended. Fertility: There are no adequate safety data. ***4.7. Effects on ability to drive and use machines:*** *No studies have been performed regarding 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), unknown (cannot be estimated from the available data). Gastrointestinal diseases: Common: Nausea, vomiting, diarrhoea No undesirable effects other than these have been reported so far. ***4.9. Overdose and Treatment:*** *No overdose of pumpkin seed oil has been reported so far. Pumpkin seed oil taken orally can be well-tolerated; no effect related to* overdose is expected. Nevertheless, if any symptom arises after overdose, the treatment should be symptomatic and supportive. It has no specific antidote and method to enhance its elimination. ***5. PHARMACOLOGICAL PROPERTIES:*** *The pharmacotherapeutic group (ATC code) has not been identified yet.* ***5.1 Pharmacodynamic properties:*** *Pumpkin seed oil has been* used as a herbal medicinal product for centuries. Pumpkin seed oil has many different pharmacological effects due to the fact that it has a large variety of substances in its composition and each of these has different therapeutic efficacies. Pumpkin seeds are rich in phytosterols, tocopherols and essential fatty acids (mostly linoleic and oleic acids) and the supposed active ingredients contained in pumpkin seeds are Δ7-sterols (avenasterol and spinasterol) and Δ5-sterols (sitosterol, stigmasterol). Pumpkin seed oil inhibits enzyme 5α-*reductase. Thus it is* reported it has helped the treatment of diseases related to prostate gland by preventing the conversion of testosterone into dihydrotestosterone (DHT). Many non-clinical and clinical trials have been conducted in order to investigate the effects of pumpkin seed oil on benign prostatic hyperplasia. In the clinical trials conducted, it has been demonstrated that pumpkin seed oil can be used to help the treatment of benign prostatic hyperplasia and administered in a clinically safe manner. The effect of pumpkin seed oil on urinary incontinence that is one of the most frequent problems in postmenopausal women and in men at later ages has been investigated in a large number of clinical trials. The substances contained in pumpkin seed oil are demonstrated to have anabolic effects on pelvic muscles. It is reported that the contraction of pelvic muscles has grown stronger due to these effects. Also, nitric oxide is needed for relaxation of muscles when the bladder gets full and for performance of the function of urinating. When the nitric oxide synthesis is inhibited, the bladder activity increases and the bladder volume decreases. It is reported that pumpkin seed oil prevents urinary incontinence by relaxing bladder muscles when the bladder gets full through nitric oxide. It is reported that pumpkin seeds decrease urinary incontinence due to these double effects on pelvic muscles and on nitric oxide. Also pumpkin seed oil is demonstrated to have effects that are adjuvant to the treatment of urinary tract infections especially such as cystitis. Pumpkin seed oil has been used for many years as an adjuvant to the anthelmintic (schistosomiasis, taenia, etc.) treatment. In a clinical trial conducted, it has been demonstrated that pumpkin seeds can help for Schistosomiasis which is a serious parasitary disease primarily spread through snails in Asia and Africa. Also in the studies conducted, it has been reported that pumpkin seeds can help the treatment of taenia. ***5.2. Pharmacokinetic properties General properties:*** *There are no data regarding the absorption, dispersion, metabolism and elimination of pumpkin seed oil.* ***6. PHARMACEUTICAL PARTICULARS 6.1. List of excipients:*** *dl α-tocopherol, dl α-tocopheryl acetate, Gelatin, Glycerine, Pure water* ***6.2. Incompatibilities:*** *Not known* ***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.* ***7. MARKETING AUTHORISATION HOLDER:*** *Helvacızade Gıda İlaç Kimya San ve Tic. A.Ş. Address: Fevzi Çakmak Mah. Ankara Yoluüzeri 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:*** *2016/825* ***9. DATE OF FIRST AUTHORISATION OR RENEWAL OF THE AUTHORISATION Date of first authorisation:*** *21.11.2016*