ZADE VİTAL CORVİTAL

ZADE VITAL CORVITAL 625 MG SOFT GELATIN CAPSULES 1. NAME OF THE PRODUCT: *ZADE VITAL CORVITAL 625 mg soft gelatin capsules* ***2. QUALITATIVE AND QUANTITATIVE COMPOSITION*** *Active ingredient: Each soft gelatin capsule contains 625 mg of flax (Linumusitatissimum L.) seed oil (OleumLini). Excipients: 0.161 g of glycerine. For the full list of* excipients, see section 6.1. ***3. PHARMACEUTICAL FORM:*** *Soft gelatin capsules. Transparent, yellowish, oblong soft gelatin capsules* ***4. CLINICAL PARTICULARS 4.1. Therapeutic*** **indications:** *ZADE VITAL CORVITAL is rich in alpha-linolenic acid (ALA) which is a plant-based Omega 3 fatty acid. It helps treat patients with chronic constipation. Also it helps treat* cardiovascular system diseases and mild gastrointestinal diseases, and regulate certain blood lipid (fat) levels. ZADE VITAL CORVITAL can be used as a source of plant-based omega 3 (ALA) in people who cannot consume fish oil, especially vegetarians. ***4.2. Posology and method of administration Posology/frequency and duration of administration:*** *Unless otherwise* recommended by the physician, the dose of ZADE VITAL CORVITAL for adults (over 18 years of age) is 2 to 4 capsules 2 times a day (at a dose of 1250 to 2500 mg/day) taken orally. The dose of ZADE VITAL CORVITAL for children over 12 years of age is 1 to 2 capsules 2 times a day (625 to 1250 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: ZADE VITAL CORVITAL should not be used in children under 12 years of age. Geriatric population: No adequate safety studies have been performed in elderly patients. However, no dosage adjustment is considered necessary. ***4.3.*** **Contraindications:** *It should not be used in those who are allergic to the active substance or any ingredient of ZADE VITAL CORVITAL, during pregnancy and lactation, and in patients with* hepatic and renal failure, those with undiagnosed rectal bleeding, those having defecation disorders after using laxatives, patients with sudden changes observed in bowel habits for more than 2 weeks, and patients with intestinal paralysis, megacolon, and ileus. ***4.4. Special warnings and precautions for use:*** *Each capsule contains 0.161 g of glycerine. However, no adverse* effect related to such dose of glycerine is expected. The daily dose of ZADE VITAL CORVITAL should not exceed 3 g in patients taking oral anticoagulants. It should be used cautiously during the treatment of hormone-related tumours due to its oestrogenic effect. In patients with intestinal paralysis, and ileus, it should be used under supervision of a physician. It is recommended that the use of ZADE VITAL CORVITAL for more than 1 week should be consulted with a physician. ***4.5. Interaction with other medicinal products and other forms of interaction:*** *The daily* dose of ZADE VITAL CORVITAL should not exceed 3 g/day in patients taking oral anticoagulants. No interaction studies have been performed with other drugs or medicinal products. 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:*** *Since no studies have been* performed regarding this issue, it should not be used. Pregnancy: There are no clinical data regarding the exposure to flax 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 CORVITAL during pregnancy is not recommended. Lactation period: Since its safety in lactation is not proven, the use of ZADE VITAL CORVITAL 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: Meteorism Very rare: Hypersensitivity reactions resembling to anaphylaxis Unknown: Nausea, vomiting, diarrhoea No undesirable effects other than these have been reported. ***4.9. Overdose and Treatment:*** *No overdose of flax seed oil has been reported. Flax seed oil taken orally can be well-tolerated. However, it is* reported that overdose in the oral use of flax seeds may lead to abdominal disorders such as flatulence, dyspepsia. 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:*** *Flax seeds contain fats high in omega-3, digestible proteins and lignans. Flax seeds are prominent among other oils extracted from* seeds due to the fact that they contain a high amount of linolenic acids (ALA, 18:-linolenic acids (ALA, 18:3n-3) and lignans. Flax seeds contain 35-45% fat, and 45% to 52% of this fat content consists of ALAs. ALAs are classified as omega-3 fatty acids. Flax seed oil has many different pharmacological effects due to ALAs in its composition. It is demonstrated that flax seed oil generally leads to a 15% decrease in serum total cholesterol levels. Also in a study conducted, it is reported that the use of flax seed oil containing a high amount of ALAs has lowered serum total cholesterol, LDL (low-density lipoprotein) levels in people with hyperlipidemia. Also in postmenopausal women, a similar reduction has been observed in LDL cholesterol levels. It is reported that this effect is caused by SDG (secoisolariciresinol diglucoside) compounds which are isolated from flax seeds, and are the precursors of mammalian lignans called enterodiol and enterolactone, and a 33% reduction in the amount of serum total cholesterol, and a 73% reduction in atherosclerotic plaques have occurred. These actions of flax seed oil account for its effect that prevents the development of atherosclerosis and regulates blood lipid levels. In the studies conducted, it is reported that flax seed oil has antithrombotic effects and platelet aggregation-reducing effects, and accordingly it may reduce the incidence of thrombosis. Flax seed oil has antioxidant effects due to its ALA content. Also, ALAs have suppressor effects on Interleukin, TNF (Tumour necrosis factor), leukotriene B4 and polymorphonuclear leukocytes. These actions account for the effects of flax seed oil which inhibit the development of inflammation. Flax seed oil is known to increase the absorption of calcium. Along with this effect, it is reported to have effects that help bone health. In addition to the fact that flax seeds are good nutritional sources due to the fibrous structures they contain, they are also known to increase bowel movements in adults. In the studies conducted, it is demonstrated that the frequency and continuity of defecation in those using flax seed oil have improved. Also, flax seed oil is of importance in that it is a plant-based Omega 3 support for adults who cannot consume fish oil, especially vegetarians. ***5.2. Pharmacokinetic properties:*** *There are no data regarding the absorption, dispersion, metabolism and elimination of flax 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 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:*** *2016/856* ***9. DATE OF FIRST AUTHORISATION OR RENEWAL OF THE AUTHORISATION Date of first authorisation:*** *02.12.2016.*