ZADE VITAL ROTAVIN

ZADE VITAL ROTAVIN 500 MG SOFT GELATIN CAPSULES 1. NAME OF THE PRODUCT: *ZADE VITAL ROTAVIN 500 mg soft gelatin capsules* ***2. QUALITATIVE AND QUANTITATIVE COMPOSITION Active ingredient:*** *Each soft gelatin capsule contains 500 mg of grape seed oil (Oleum Vitis viniferae seminis) extracted from seeds of the plant Vitis vinifera L. through cold* pressing. Excipients: 80.5 mg 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 ROTAVIN is rich in essential fatty acids. Due to its antioxidant activity, it is used to help regulate certain* blood lipid levels, treat hypertension, reduce chronic venous insufficiency-related symptoms (such as pain, feeling of somnolence, nocturnal cramps, itchy and swollen legs), treat varicose veins, and reduce haemorrhoid symptoms (pain, exudation, itching and bleeding) and their complications. ***4.2. Posology and method of administration Posology/frequency and duration*** **of administration:** *Unless otherwise recommended by the physician, the dose of ZADE VITAL ROTAVIN for adults over 18 years of age is 2 to 4 capsules per day (at a dose of 1000-2000 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 ROTAVIN should not be used in children under 18 years of age and adolescents. Geriatric population: No adequate safety 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 other ingredient of VITAL ROTAVIN,* 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 ROTAVIN should not exceed* 3 g in patients taking oral anticoagulants. ZADE VITAL ROTAVIN contains glycerine. It requires no warning due to its amount. It is recommended that the use of ZADE VITAL ROTAVIN 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 ROTAVIN* 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 Women of childbearing potential/Contraception Pregnancy:*** *There are no clinical data regarding the use of grape seed oil in pregnant women.* The studies conducted in animal subjects are not adequate for the effects on pregnancy, embryonic/fetal development, birth and/or post-birth development. There are no adequate data regarding the use together with oral contraceptives. Since no adequate studies have been performed regarding its use during pregnancy, the use of ZADE VITAL ROTAVIN during pregnancy is not recommended. Lactation period: Since no adequate studies have been performed regarding its use during lactation, the use of ZADE VITAL ROTAVIN during lactation is not recommended. Fertility: There are no adequate data on fertility. ***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 Gastrointestinal diseases:*** *No undesirable effects other than nausea, vomiting, and diarrhoea have been reported.* ***4.9. Overdose and Treatment:*** *No* overdose of grape seed oil has been reported. Grape seed oil taken orally can be well-tolerated; in case of overdose, no effect is expected. 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:*** *Grape seed oil has many* functional properties and has a composition that is quite rich in content. Grape seed oil contains 58-78% of linoleic acid and 900 to 1200 ppm of tocopherol. These tocopherols it contains are one of the most powerful fat-soluble antioxidants, and with respect to this property, it is 50 times more effective than vitamin E and 20 times more effective than Vitamin C. The grape seed oil produced through cold pressing is found to be more powerful than those produced through other methods in terms of the compounds such as antioxidative phenolic compounds that are good for health. While it lowers the LDL (low-density lipoprotein) level due to these powerful antioxidant effects, it increases the HDL (high-density lipoprotein) level. In the clinical trials, it is determined that the intake of grape seed oil in daily diet has apparently regulated the HDL and LDL levels in the short-term treatment in cases where the weight is fixed and the low HDL level is observed. In the study conducted in 33 patients, the intake of grape seed oil in daily diet for 4 weeks is demonstrated to increase the HDL level and lower the triglyceride level in dyslipidemic patients. The phenolic compounds contained in grape seed oil help protect cardiovascular health due to their antioxidant effects. Grape seed oil is used to help reduce chronic venous insufficiency-related symptoms (such as pain, feeling of somnolence, nocturnal cramps, itchy and swollen legs), treat varicose veins, and reduce haemorrhoid symptoms (pain, exudation, itching and bleeding) their complications. ***5.2. Pharmacokinetic properties:*** *There are no data regarding the absorption, dispersion, metabolism and elimination of grape 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*