

## ZADE VITAL NIGELIN

**ZADE VITAL NIGELIN 900 MG SOFT GELATIN CAPSULES:** Each soft gelatin capsule contains 900 mg black cummin (*Nigellasativa*) seed oil.

**PHARMACOLOGICAL PROPERTIES:** It is shown in the analyses performed by high-performance liquid chromatography (HPLC) that there are four main active substances in *Nigellasativa* oil. These are thymoquinone (TQ), dithymoquinone (DTQd), thymohydroquinone (THQ, nigellon) and thymol (THY). Some of these are immunomodulatory, antioxidant and blood lipid level regulating activities. Black cummin (*Nigellasativa*) seed oil directly increases immune resistance in the elderly. Black cummin (*Nigellasativa*) T cells have the ability to enhance its effect on the immune system. It is reported that black cummin (*Nigellasativa*) seed oil can be used to support the treatment of hyperlipidemia, thereby inhibiting lipid peroxidation and preventing the development of atherosclerosis in users. The active ingredients of black cummin (*Nigellasativa*) seed oil are shown to be effective in inflammatory diseases caused by histamine. *Nigellasativa* oil is shown to reduce immunoglobulin E (IgE) and eosinophil count and endogenous cortisol in plasma and urine in allergic diseases such as allergic rhinitis, bronchial asthma and atopic asthma, and it is reported that the use of *Nigellasativa* oil as an adjuvant in the treatment of allergic diseases, especially in the treatment of allergic rhinitis, may have positive effects. **INDICATIONS:** ZADE VITAL NIGELIN is rich in essential fatty acids. It is used to boost the immune system due to its antioxidant properties and also to help regulate certain blood lipid (fat) levels and treat allergic rhinitis. **CONTRAINDICATIONS:** It should not be used in those who are allergic to the active substance or any ingredient of ZADE VITAL NIGELIN, during pregnancy, and in patients with hepatic and renal failure. **WARNINGS AND PRECAUTIONS:** The daily dose of ZADE VITAL NIGELIN should not exceed 2.7 g/day in patients taking oral anticoagulants. It requires no warning due to the excipients it contains. ZADE VITAL NIGELIN should not be used during pregnancy due to the antitoxic effects of black cummin (*Nigellasativa*) seed oil. 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. Since no adequate safety studies have been performed in children under 6 years of age and they may have difficulty in swallowing capsules, its use in children under 6 years of age is not recommended due to the risk of suffocation. Black cummin (*Nigellasativa*) seeds are used as galactagogues among the public. However, a physician should be consulted regarding its use during lactation. **SIDE EFFECTS/ADVERSE EFFECTS:** The use of ZADE VITAL NIGELIN may cause adverse effects pertaining to the gastrointestinal system such as nausea, vomiting, diarrhoea, although their frequency is not known. No undesirable effects other than these have been reported. **CONSULT YOUR PHYSICIAN IN CASE OF AN UNEXPECTED EFFECT.** **DRUG INTERACTIONS:** No interaction studies have been performed with other drugs or medicinal products. **METHOD OF ADMINISTRATION AND DOSE:** Unless otherwise recommended by the physician, the dose of ZADE VITAL NIGELIN for adults is 2 to 4 capsules per day (at a dose of 1800 to 3600 mg/day) taken orally. The dose of ZADE VITAL NIGELIN for children over 6 years of age, who can swallow capsules, is 1 to 3 capsules per day (40 to 80 mg/kg/day) taken orally. **MARKETING AUTHORISATION DATE AND NUMBER:** 21.01.2014 - 2014/15 for ZADE VITAL NIGELIN 900 MG SOFT GELATIN CAPSULES. **MARKETING AUTHORISATION HOLDER NAME AND ADDRESS:** Helvacizade Gıda İlaç Kimya San ve Tic. A.Ş. Fevzi Çakmak Mah. Ankara Yolu üzeri 6. km. 42050 Konya. **MANUFACTURING COMPANY NAME AND ADDRESS:** Biofarma İlaç San. ve Tic. A.Ş. Akpınar Mah. Osmangazi Cad. No: 156 Sancaktepe/İstanbul. **STORAGE CONDITIONS:** Keep out of the reach and sight of children and keep in its own package. Store at room temperature below 25°C. **FORM OF PRESENTATION AND PRICE:** In blister packs for ZADE VITAL NIGELIN 900 mg 60 soft gelatin capsules and 96.89 TL (July 2016). SPC approval date: 11.03.2014.