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D O S S I E R

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On the Subject

Black Cumin Oil

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DOSSIER On the Subject of Black Cumin Oil

1. Description and Constituents

Black cumin or Nigella sativa is a tall annual with finely divided, linear leaves, white flowers and capsules containing black seeds. It originates from Southern Europe, North Africa and Western Asia. The seeds or rather the seed oil is used. Black cumin has been used for centuries for a variety of conditions in Arab and Islamic traditional medicine.[1]
The seeds contain oil high in fat (up to 40% triglycerides) with phytosterols and an essential oil that is rich in thymoquinone, p-cymene and thymol. Furthermore, it contains alpha-hederin (a triterpensaponin), nigellon, triglycosides of quercetin and kaempherol and, lastly, nigellin, a single alkaloid that gives black cumin oil its typical scent.

2. Effects

In animal experiments, thymoquinone and nigellon have exhibited a large number of positive effects. They inhibit the 5-lipoxygenase as well as the inducible nitric oxide synthase, and are therefore **beneficial in the treatment of inflammations**. In publications over recent years, they have additionally been **shown to have blood-sugar lowering, antioxidant, liver protective, antithrombotic, antispasmodic and bronchodilating effects, as well as antibacterial effects.[1]**
A review of **4 studies conducted on a total of 152 patients with allergic diseases** who were administered 40-80 mg oil per kg of body weight per day resulted in **beneficial effects** on the patients' well-being. However, their lymphocyte levels remained unchanged. There was a slight decrease in plasma triglycerides and a discrete **increase in HDL cholesterol.[2]**

Black cumin oil has been used for centuries to season and preserve foods. The ingredient thymoquinone has been attracting increasing interest.
A review of studies on Nigella sativa gave clear evidence of its **antioxidant effects**. The oil and its active components, predominantly thymoquinone, act as **radical scavengers**. In addition, **antimicrobial and immunomodulatoric properties** were established. [3]
In vitro, the mechanism of action was demonstrated, by which black cumin oil triggers **anti-inflammatory effects**. Cyclooxygenase enzymes that are necessary for the synthesis of leukotrienes and prostaglandins, are inhibited. [4]
A study on diabetic rats investigated the **effect Nigella sativa had on bone density**, connectivity and the biomechanics of bones. The combination of Nigella sativa and the parathyroid hormone turned out to be very effective. [5]

Black cumin oil inhibits the activity of the neutrophil elastase (has destructive effects, e.g. on pulmonary cells, *note*). It could thus be used to treat wounds or injuries or even chronic obstructive pulmonary diseases. [6]
Thymoquinone was identified as the most important component of black cumin oil. **The oil protects against substances toxic to the liver and kidneys. It has anti-**

inflammatory and antimicrobial effects and lowers blood pressure. These effects are based on the agents thymoquinone and its cytoprotective and antioxidant properties. [7]
Over the recent years, many studies were conducted on black cumin seeds that showed its **immunological and anti-inflammatory potential.** A study on rats showed **that the thymoquinones contained in the oil suppressed arthritis.** In this test, the animals were given at least 2.5mg for every kg of their body weight.

In experiments with guinea pigs, Nigella sativa achieved anticholinergic and relaxing effects. **A study on more than 29 persons suffering from asthma underlined these effects. After 45 days, the subjects' symptoms showed significant improvement. The results suggest that Nigella sativa has a prophylactic effect on respiratory diseases.** [9]
In an animal experiment, rats were administered 0.1 ml black cumin oil per kg body weight. **After 12 weeks, the animals had lower cholesterol levels, lower blood glucose levels and lower blood triglycerides than before.** [10]
In a study on rats, black cumin oil, acting as a radical scavenger, proved successful in protecting the stomach lining from damages caused by alcohol. Normally, after alcohol consumption an oxidative parameter called TBARS (Thiobarbituric acid reactive substances) is increased. The oil was able to stop this increase. [11]
Another study showed that rats that were given up to 500 mg of black cumin oil per day for two weeks had **lower blood glucose levels** after the end of the period. [12]

An in-vitro study showed that Nigella sativa exhibited an inhibitory effect on nitric oxide production by macrophages. NO is considered to be an indicator of inflammation, which is why black cumin oil is thought to be **beneficial for the treatment of rheumatism**.[13]
In a study with albino rats, Nigella sativa exhibited anti-atherogenic effects. The administration of 30 mg of the oil per kg of body weight over a period of eight weeks led to a **significant reduction in LDL cholesterol and an increase in "good" HDL cholesterol.** In a study conducted in Egypt, 10 mg of thymoquinone were administered. Likewise, there was a **significant improvement in the blood lipid levels.**[14]
A study was conducted for two four-week periods on 15 healthy female subjects to compare the impact of fish oil and black cumin oil on lipid levels. The subjects were given 3 g of black cumin oil and 2.8 g fish oil per day. Fish oil was shown to be more efficient in lowering plasma glucose and led to a significant increase in the plasma levels of eicosapentaenoic acid and docosahexaenoic acid, but black cumin oil was shown to be more efficient in **reducing LDL-cholesterol and also led to higher levels of gamma linolenic acid.**[15]

3. Toxicity
Black cumin oil has a very low toxicity. Two cases of contact dermatitis after use were reported. Apart from that, no adverse effects were recorded. There are no negative effects on the kidney or the liver.[7] Studies on rats suggest that black cumin oil has immunosuppressive effects and is cytotoxic.[16]
In a study, rats with a weight of approx. 200 g were given up to 500 mg of black cumin oil a day over a period of two weeks. All test animals tolerated these quantities well and there was no harm to their health. Extracts of thymoquinone were also well

tolerated up to a dose of 6 mg per day. Only in the case of 8 mg were there toxicological incidents.[12]
The toxicity of black cumin oil was examined more closely in animal experiments. A dose of 2 ml per kg of body weight did not lead to chronic toxicity after 12 weeks. There were no adverse effects on the liver, on aminotransferases and there were no histopathological modifications in the kidneys, pancreas or heart. Based on this, black cumin oil has a very low toxicity. However, a constant use may lead to a modification in the haemoglobin metabolism and a reduced number of leucocytes. These effects require closer examination.[17] In a study on acute toxicity in mice, Nigella sativa was inconspicuous. Nor could chronic toxicity be detected. But it should be considered that a watery essence of the seeds may damage the liver.[18]

4. Evaluation and résumé

Black cumin oil consists of phytosterols, thymoquinone, p-cymene and thymol. In studies, thymoquinone has been shown to be a very active and the most important component with regard to the effects of black cumin oil.
The spectrum of its effectiveness established in studies is very broad. **Black cumin oil, most importantly, has anti-inflammatory effects**, because it suppresses the formation of prostaglandins and leukotrienes (by inhibiting cyclooxygenase) or inhibits their effect. Furthermore, antioxidative effects have been determined. There was also a clear effect on the lipid levels. **Black cumin oil lowers LDL cholesterol and raises HDL cholesterol.** Occasionally, it has also been shown to lower triglyceride levels. Many of these effects were already proven in animal experiments, **but some human studies are already available too.** Beyond the described effects we can only speculate. Protection of the gastric mucosa, **help with asthma or rheumatism, relief in skin diseases** are just a few examples; effects in these directions have been established, however a wide variety of proof is still lacking.

The EU Directive 1999/21/EC on dietetic food for special medicinal purposes provides that such food products comply with the nutritional requirements of persons suffering from certain diseases, disorders or ailments. This must be proven by scientific data. They are intended for the exclusive or partial nutrition of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites.
A distinction is drawn between:

nutritionally complete foods with a standard nutrient formulation which may constitute the sole source of nourishment and

nutritionally complete foods with a nutrient-adapted formulation which may constitute the sole source of nourishment and

nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.[19]

Based on these categories, the product clearly belongs in the third group. The improvement in lipid levels, its anti-inflammatory effect, and possibly also its antioxidant effect all have a favourable effect on a series of diseases. However, based on these effects, it is hardly possible to determine a specific effect against a certain disease.

Black cumin oil has a very low toxicity. No animal experiments produced any evidence for chronically toxic effects either. In none of the human studies described

in this Dossier did adverse effects occur. In several tests on animals, experiments with isolated thymoquinone were conducted that mostly proceeded without inducing any adverse effects on health. Only in one case did a dose of 8 mg per kg body weight prove to be toxic. In another study, however, the administration of as much as 10 mg per kg body weight remained without consequence.
The product in question, when applied in a daily dose of 1.8 g oil, may therefore be considered as safe.

5. Market Overview
Black cumin oil, e.g. the Embamed brand, is available at every Austrian pharmacy under the Pharmaceutical Central Number: PZN 1794427
Black cumin oil is also sold at online shops.
You can buy black cumin oil from many websites, most of which are in the EU.
e.g. Embamed HandelsgesmbH, www.embamed.at
or GALL PHARMA GmbH, www.gall.co.at

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