

NicAzel[®]FORTE

(Azerizin[®], zinc, pyridoxine, copper, folic acid)

Prescription Dietary Supplement

DESCRIPTION

NicAzel FORTE Tablets is a uniquely formulated dietary supplement for oral administration. Each green-colored, oval-shaped tablet is imprinted on one side with “EL510” and contains Azerizin[®], a proprietary blend of natural ingredients that combine demonstrated anti-inflammatory and antimicrobial properties, along with inhibiting effects on sebum production.

Ingredients:

Each oral tablet provides:

Azerizin [®] *	700 mg
Zinc (Zinc Oxide)	12 mg
Pyridoxine (Vitamin B6).....	8 mg
Copper (Cupric Oxide).....	2 mg
Folic Acid	500 mcg

*Azerizin[®] is a proprietary blend of Nicotinamide, Azelaic Acid, Quercetin and Curcumin.

Other Ingredients:

Microcrystalline cellulose, stearic acid, green coating (polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, FD&C Blue #1, FD&C Yellow #5, FD&C Yellow #6), silicon dioxide, magnesium stearate, dibasic calcium phosphate.

CLINICAL PHARMACOLOGY

Nicotinamide is a water-soluble component of the vitamin B complex group. In vivo, nicotinamide is incorporated into nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). NAD and NADP function as coenzymes in a wide variety of enzymatic oxidation-reduction reactions essential for tissue respiration, lipid metabolism, and glycogenolysis.

Nicotinamide has demonstrated anti-inflammatory actions that may be of benefit in patients with acne including, but not limited to, suppression of antigen-induced lymphocytic transformation and inhibition of 3', 5'-cyclic AMP phosphodiesterase. Nicotinamide has been demonstrated to block the inflammatory actions of iodides known to precipitate or exacerbate acne.

Nicotinamide lacks the vasodilator, gastrointestinal, hepatic, and hypolipemic actions of nicotinic acid or niacin. As such, nicotinamide has not been shown to produce the flushing, itching, and burning sensations of the skin, as is commonly seen when large doses of nicotinic acid or niacin are administered orally.

Azelaic acid is a dietary constituent (eg, in whole grain cereals and animal products) that has been shown to possess antimicrobial activity against *Propionibacterium acnes* and *Staphylococcus epidermidis*. The antimicrobial action may be attributable to inhibition of microbial cellular protein synthesis. A normalization of keratinization leading to an anticomedonal effect of azelaic acid may also contribute to its topical use for inflammatory acne vulgaris and rosacea.

Quercetin is a polyphenolic substance and a member of the class of flavonoids called flavonols. Quercetin is widely distributed in the plant kingdom, with onions, apples, red wine, and green tea especially rich sources of the agent. Quercetin is an antioxidant that inhibits lipid peroxidation. Its potent anti-inflammatory activity is at least in part accounted for by its inhibition of degranulation of mast cells, basophils and neutrophils, coupled with its modulation of the activity of the inflammatory mediator NF-kappa B. Quercetin has been reported to reduce inflammation in both acne and rosacea.

Curcumin is a polyphenolic substance principally found in the spices turmeric and ginger. Curcumin has been demonstrated to have antioxidant, anti-inflammatory, and antimicrobial activities, and has been clinically most widely evaluated for its purported anti-cancer and cancer chemopreventive properties. Curcumin has been widely employed in the management of acne vulgaris and rosacea, based on its significant inhibition of *Propionibacterium acnes* and its potent anti-inflammatory actions, which include inhibition of cyclooxygenase (COX) and lipoxygenase (LOX), reduction of the release of reactive oxygen species (ROS) by stimulated neutrophils, and its inhibition of the activation of proinflammatory cytokines.

Pyridoxine or Vitamin B6 is a water soluble component of the vitamin B complex group, which in the form of the coenzyme pyridoxal 5'-phosphate, is involved in a wide range of biochemical reactions, and is present in a wide variety of food sources including meat, poultry, fish, eggs, starchy vegetables, and non-citrus fruits. Pyridoxine plays an active role in the immune system and supplementation to normal levels in individuals with even a marginal deficiency generally restores immune functions due to deficiency. Pyridoxine supplementation has been found helpful in the management of acne, particularly for women with premenstrual flares of acne.

Zinc has been shown to inhibit the inflammatory polymorphonuclear leukocyte chemotaxis in acne patients. Zinc has also demonstrated an inhibitory effect on the lipase of the three *Propionibacterium* species found in human pilosebaceous follicles. Patients with acne have been shown to have significantly lower serum zinc levels than matched healthy controls.

Copper is an essential trace mineral in human nutrition. Although rare, copper deficiency has been induced by supplemental zinc therapy.

Folic acid serves as an essential cofactor of the biosynthesis of thymidine and purine nucleotides required for normal cellular DNA synthesis. Deficiencies of folic acid have been demonstrated to occur in some cutaneous disorders.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

USE

As a dietary supplement for inflammatory skin disorders, such as acne vulgaris or rosacea, and/or individuals who are deficient in or at risk of deficiency in one or more of the components in NicAzel FORTE Tablets.

WARNINGS

As with any dietary supplement, if you are pregnant, nursing or taking medication, consult your doctor before use. NicAzel FORTE Tablets is not formulated for use in children under six years of age.

PRECAUTIONS

Allergic sensitization has been reported rarely following oral administration of folic acid.

Folic acid above 1 mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations remain progressive.

DOSAGE AND ADMINISTRATION

Usual adult dose is one or two tablets taken once or twice a day with or without food or as prescribed by a physician.

HOW SUPPLIED

60 tablets 42783-510-60

4 tablets 42783-510-04 (physician sample size) Store between 15°-30°C (59°-86°F).

Manufactured for:

Elorac, Inc.

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U.S. Patent Pending Made in the USA

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