



## NicAzal™ Tablets Rx Only

### DESCRIPTION

Nicazel Tablets is a dietary supplement for oral administration. Each tablet is purple-colored, oval-shaped, and embossed with "EL501" on one side.

### Ingredients:

Each oral tablet provides:

|                           |         |
|---------------------------|---------|
| Nicotinamide (Vitamin B3) | 600 mg  |
| Azelaic Acid              | 5 mg    |
| Zinc (Zinc Oxide)         | 10 mg   |
| Pyridoxine (Vitamin B6)   | 5 mg    |
| Copper (Cupric Oxide)     | 1.5 mg  |
| Folic Acid                | 500 mcg |

### Other Ingredients:

Microcrystalline cellulose, stearic acid, purple coating (polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, FD&C Blue #2, FD&C Red #40), silicon dioxide, magnesium stearate

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

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 (e.g., 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 clinical activity.

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 patients with acne vulgaris, rosacea, or other inflammatory skin disorders who are deficient in or at risk of deficiency in one or more of the components in Nicazel Tablets.

### WARNINGS

As with any dietary supplement, if you are pregnant, nursing or taking medication, consult your doctor before use. Nicazel Tablets is not formulated for use in children under 6 years of age.

Folic acid above 1 mg daily may obscure pernicious anemia (hematologic remission may occur, while neurological manifestations remain progressive).

### PRECAUTIONS

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

### 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 NDC 42783-501-60  
4 tablets NDC 42783-501-04 (physician sample size)

Store between 15°-30°C (59°-86°F).

Manufactured for  
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U.S. Patent Pending

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