

NICAZEL- nicotinamide, pyridoxine, zinc, copper, folic acid tablet, coated
Elorac, Inc

NicAzel®
Dietary Supplement
Prescription Only

NicAzel®
(nicotinamide, zinc, azelaic acid, pyridoxine, copper, folic acid)
Prescription Only
Dietary Supplement

DESCRIPTION

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

Ingredients:

Each oral tablet provides:

Nicotinamide (Vitamin B3).....600 mg
Zinc (Zinc Oxide).....10 mg
Azelaic Acid.....5 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 no. 2, FD&C Red no. 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 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.

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.

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 be also contributed to its topical use for treatment of acne vulgaris.

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. These products are 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 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 is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient.

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 can occur while neurological manifestations remain progressive.

DOSAGE & 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

Store between 15°-30°C (59°-86°F).

Manufactured for
Elorac, Inc.

100 Fairway Drive, Ste. 134

Vernon Hills, IL 60061

Made in the USA

U.S. Patent Pending

02/2015

©2015 Elorac, Inc.

141609-3

Dosage:

Adults - One or two tablets taken once or twice a day with or without food or as prescribed by a physician.

Store between 15°-30°C (59°-86°F).

Purple-colored, oval-shaped tablets debossed "EL501" on one side.

PLEASE REFER TO PACKAGE FOLDOUT FOR WARNINGS AND PRECAUTIONS.

Keep out of reach of children.



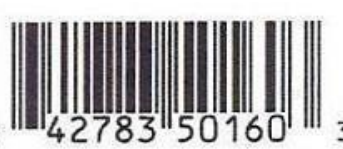
Manufactured for:
Elorac, Inc.
Vernon Hills, IL 60061

Rev. 02/15
7164-2
42783-501-60

NicAz[®]
(nicotinamide, zinc, azelaic acid, pyridoxine, copper, folic acid)

Dietary Supplement

Prescription Only
60 Tablets

<p style="text-align: center;">42783-501-60</p>  <p style="text-align: center;">(nicotinamide, zinc, azelaic acid, pyridoxine, copper, folic acid)</p> <p style="text-align: center;">Dietary Supplement</p> <p>Prescription Only 60 Tablets</p> 	<p>Dosage: Adults – One or two tablets taken once or twice a day with or without food or as prescribed by a physician.</p> <p>Store between 15°-30°C (59°-86°F).</p> <p>Purple-colored, oval-shaped tablets debossed "EL501" on one side.</p> <p>PLEASE REFER TO PACKAGE FOLDOUT FOR WARNINGS AND PRECAUTIONS.</p> <p>Keep out of reach of children.</p> <p>Manufactured for: Elorac, Inc. Vernon Hills, IL 60061</p> <p style="text-align: right;">Rev. 02/15 7164-2</p>  <p style="text-align: center;">3 42783 50160 3</p>
--	---

Lift Here

tablets taken once or
without food or as
prescribed by a physician.

Store between 15°-30°C (59°-86°F).

Purple-colored, oval-shaped tablets debossed "EL501"

PLEASE REFER TO PACKAGE FOLDOUT FOR WARNINGS AND PRECAUTIONS.

Keep out of reach of children.

Rev. 02/15
7164-2



3 42783 50160 3

nicotinamide is converted into nicotinamide ribotide (NAD) and adenosine dinucleotide (ADP). NAD and NADP are essential for many enzymatic reactions in a wide variety of metabolic processes, including lipid metabolism, glycolysis, and gluconeogenesis. Nicotinamide has been demonstrated to have a variety of biological actions that may be beneficial to patients with acne, including but not limited to: (1) inhibition of antigen-induced inflammation and (2) inhibition of 5'-cyclic AMP phosphodiesterase activity. Nicotinamide is not considered to be an irritant or sensitizer. Nicotinamide is not considered to be an irritant or sensitizer. Nicotinamide is not considered to be an irritant or sensitizer.

lacks the vasodilator, analgesic, and antipyretic actions of salicylic acid. Nicotinamide has been shown to produce the effects of vasodilation, and burning.

sensations of the skin, as is commonly seen when large doses of nicotinic acid or niacin are administered orally.

Zinc has been shown to inhibit the inflammatory polymorphonuclear leukocyte chemotaxis in acne patients. Zinc has also been demonstrated to have 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.

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

anticonemotional effect of azelaic acid may also contribute to its topical use for treatment of acne vulgaris.

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. These products are 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 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 is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient.

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 can 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 42783-501-60
Store between 15°-30°C (59°-86°F).

Manufactured for
Elorac, Inc.
100 Fairway Drive, Ste. 134
Vernon Hills, IL 60061
Made in the USA

U.S. Patent Pending
02/2015
©2015 Elorac, Inc.
141609-3

Dosage:
Adults – One or two tablets a day with or without food or as prescribed by a physician.

Store between 15°-30°C
Purple-colored, oval on one side.

PLEASE REFER TO F AND PRECAUTIONS.
Keep out of reach of children.

Manufactured for:
Elorac, Inc.
Vernon Hills, IL 60061



2.1250"

NicAzet® Tablets
Prescription Only
Dietary Supplement

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

Ingredients:
Each oral tablet provides:
Nicotinamide (Vitamin B₃) .. 600 mg
Zinc (Zinc Oxide) 10 mg
Azelaic Acid 5 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 no.2, FD&C Red no.40), silicon dioxide, magnesium stearate.

Nicotinamide is a water-soluble component of the vitamin B complex

group. In vivo incorporated into adenine dinucleotide (ADP) and nicotinamide phosphate (NADP) function as a variety of enzyme reduction reactions in tissue respiratory and glycolytic pathways. Nicotinamide is an anti-inflammatory agent. It has been shown to be of benefit in a variety of conditions including, but not limited to, suppression of lymphocytic thyroiditis, inhibition of phospholipase A₂ activity, inhibition of inflammatory responses, and treatment of acne.

Nicotinamide is a water-soluble component of the vitamin B complex

NICAZEL

nicotinamide, pyridoxine, zinc, copper, folic acid tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:42783-501
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	600 mg
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	10 mg
AZELAIC ACID (UNII: F2VW3D43YT) (AZELAIC ACID - UNII:F2VW3D43YT)	AZELAIC ACID	5 mg
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	5 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	1.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42783-501-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		10/15/2010	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	19 mm	
scoring	1	
imprint		

Labeler - Elorac, Inc (832590009)

Establishment

Name	Address	ID/FEI	Business Operations
Nexgen Pharma, Inc.		806784679	analysis(42783-501) , manufacture(42783-501)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions		108660077	pack(42783-501) , label(42783-501)

Revised: 4/2019

Elorac, Inc