NICOTINAMIDE- nicotinamide tablet
Acella Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

NICOTINAMIDE

RX Only

Dietary Supplement

DESCRIPTION: Nicotinamide Tablets is a prescription dietary supplement for oral administration, specifically formulated for the dietary management of patients with unique nutritional needs who require increased levels of one or more of the ingredients in this product. Each white-colored, oval-shaped tablet is debossed with “342” on one side and blank on the other.

Supplement Facts
Serving Size: 1 Tablet

Amount per serving:		**% Daily Value**
Nicotinamide	750 mg	4700%
Zinc (as Zinc Bisglycinate Chelate)*	27 mg	245%
Folate (as (6S)-N5-Methyl- tetrahydrofolic Acid Calcium Salt (Equivalent to 500 mcg Folic Acid, USP))	850 mcg DFE	210%
Copper (as Cupric Oxide)	2 mg	220%
Selenium (Selenium Amino Acid Chelate)	50 mcg	90%
Chromium (Chromium Amino Acid Chelate)	100 mcg	290%

OTHER INGREDIENTS: Crosscarmellose Sodium, Magnesium Stearate, Methocel K, Microcrystalline Cellulose, Silicon Dioxide and Stearic Acid. Coating contains: Hydroxypropyl Methylcellulose, Titanium Dioxide and Triacetin.

INDICATIONS: Nicotinamide Tablets is indicated for use as a dietary supplement for patients who are deficient in, or who are at risk for deficiency in one or more of the ingredients in this product.

CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

PRECAUTIONS: Large doses of Nicotinamide Tablets should be administered with caution in patients with a history of jaundice, liver disease, or diabetes. Patients with chronic liver failure and/or renal failure should exercise extreme caution in taking prescribed supplements containing copper.

Folic acid alone is improper treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations remain progressive

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.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

WARNINGS: If you are pregnant, nursing, or taking medication, consult your doctor before use. Use only under the advice and supervision of a physician if you have a history of jaundice, liver disease or diabetes. Abnormal liver function tests have been reported in persons taking daily doses of 500 mg or more of niacinamide. Folate intake should not exceed 250% of the Daily Value (1,000 mcg).

PREGNANCY & NURSING MOTHERS:

Nicotinamide Tablets is not indicated for use as a prenatal/postnatal multivitamin for lactating and nonlactating mothers. Physicians and medical practitioners should administer Nicotinamide Tablets with caution to patients who are pregnant, lactating and/or taking medication.

ADVERSE REACTIONS: Allergic sensitization has been reported rarely following oral and parental administration of Folate.

DOSAGE AND ADMINISTRATION: Take 1-2 tablets daily, as a dietary supplement, as directed by your physician.

HOW SUPPLIED: Nicotinamide Tablets are white-colored, oval-shaped tablets debossed on one side with “342”, and are supplied in bottles of 60 tablets (42192-374-60). The listed product number is not a National Drug Code. Instead, Acella has assigned a product code formatted according to standard industry practice in order to comply with the formatting requirements of pharmacy and healthcare insurance computer systems.

STORAGE: Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature.]

MANUFACTURED FOR:

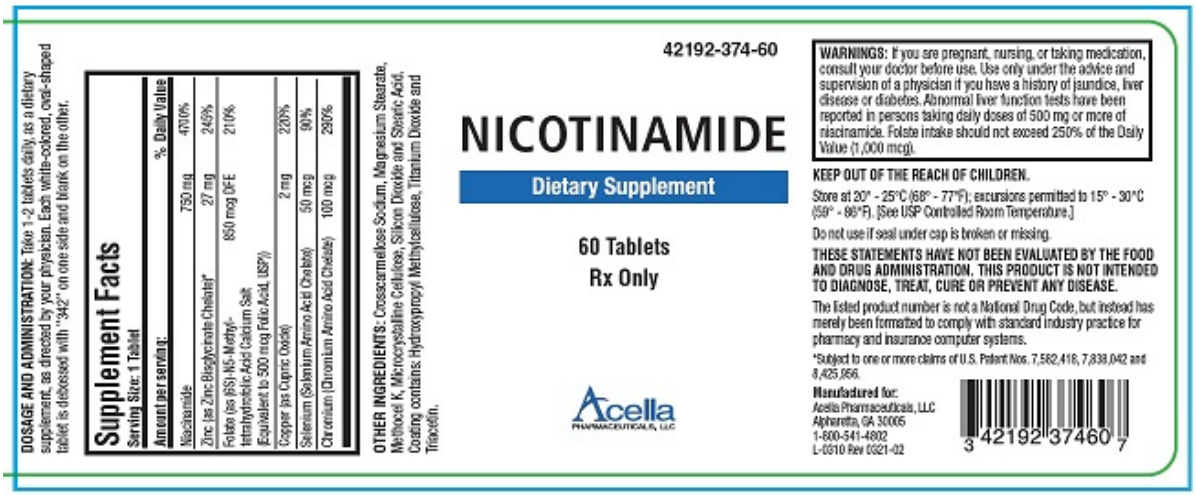
Acella Pharmaceuticals, LLC Alpharetta, GA 30005

1-800-541-4802

L-0289 Rev 0321-01

*Subject to one or more claims of U.S. Patent Nos. 7,582,418, 7,838,042 and 8,425,956.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NICOTINAMIDE

nicotinamide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-374
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	750 mg
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	27 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	850 ug
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	2 mg
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	50 ug
CHROMIUM (UNII: 0R0008Q3JB) (CHROMIUM - UNII:0R0008Q3JB)	CHROMIUM	100 ug

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	23mm
Flavor		**Imprint Code**	342
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-374-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/25/2021	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Acella Pharmaceuticals, LLC (825380939)

Revised: 10/2023 Acella Pharmaceuticals, LLC