

NICOMIDE- niacinamide, zinc glycinate, folic acid, cupric oxide, selenium and chromium tablet

Avion 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.

Nicomide®

Rx Only Dietary Supplement

DESCRIPTION

Nicomide® 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
Niacinamide	750 mg	†
Zinc (as Zinc Bisglycinate Chelate)*	27 mg	180%
Folate (as (6S)-N5-Methyltetrahydrofolic Acid Calcium Salt)	500 mcg	125%
Copper (as Cupric Oxide)		100%
Selenium (Selenium Amino Acid Chelate)		71%
Chromium (Chromium Amino Acid Chelate)		83%

† Daily Value (DV) not established.

OTHER INGREDIENTS

Methocel K, Lactose Anhydrous, Silicon Dioxide, Stearic Acid, Microcrystalline Cellulose, Magnesium Stearate, Hydroxypropyl Methylcellulose, Triacetin, and Titanium Dioxide.

INDICATIONS

Nicomide® 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 Nicomide® 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

Nicomide[®] Tablets is not indicated for use as a prenatal/postnatal multivitamin for lactating and nonlactating mothers. Physicians and medical practitioners should administer Nicomide[®] 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

Nicomide[®] Tablets are white-colored, oval-shaped tablets debossed on one side with "342", and are supplied in bottles of 60 tablets (75854-343-60). The listed product number is not a National Drug Code. Instead, Avion 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:

Avion Pharmaceuticals, LLC
Alpharetta, GA 30022
1-888-61-AVION
Rev. 1117-01

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

Nicomide® is a registered trademark of Acella Pharmaceuticals, LLC. Under license from Acella Pharmaceuticals, LLC. All rights reserved.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

75854-343-60

Nicomide®

Dietary Supplement

60 Tablets

Rx Only

Avion

PHARMACEUTICALS

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).

KEEP OUT OF THE REACH OF CHILDREN.

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

Do not use if seal under cap is broken or missing.

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.

The listed product number is not a National Drug Code, but instead has merely been formatted to comply with standard industry practice for pharmacy and insurance computer systems.

75854-343-60

Nicomide®

Dietary Supplement

**60 Tablets
Rx Only**

DOSAGE AND ADMINISTRATION: Take 1-2 tablets daily, as a dietary supplement, as directed by your physician. 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	
Niacinamide	750 mg	†
Zinc (as Zinc Bisglycinate Chelate)*	27 mg	180%
Folate (as (6S)-N5-Methyltetrahydrofolic Acid Calcium Salt)	500 mcg	125%
Copper (as Cupric Oxide)	2 mg	100%
Selenium (Selenium Amino Acid Chelate)	50 mcg	71%
Chromium (Chromium Amino Acid Chelate)	100 mcg	83%
† Daily Value (DV) not established.		

OTHER INGREDIENTS: Methocel K, Lactose Anhydrous, Silicon Dioxide, Stearic Acid, Microcrystalline Cellulose, Magnesium Stearate, Hydroxypropyl Methylcellulose, Triacetin, and Titanium Dioxide.

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

Manufactured for:
Avion Pharmaceuticals, LLC
Alphaetta, GA. 30022
1-888-61-AVION
Rev. 1117-02

3 75854 34360 14

NICOMIDE

niacinamide, zinc glycinate, folic acid, cupric oxide, selenium and chromium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75854-343
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	750 mg
ZINC GLYCINATE (UNII: 681VJX72FE) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLYCINATE	27 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	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
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:75854-343-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2014	

Labeler - Avion Pharmaceuticals, LLC (040348516)

Registrant - Avion Pharmaceuticals, LLC (040348516)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-343)