

NICAPRIN- nicotinamide, folic acid, pyridoxine hydrochloride, cupric oxide, zinc oxide, and soliprin tablet

Artesa Labs, LLC

NICAPRIN™

Rx Only Dietary Supplement

DESCRIPTION:

This product 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 tan colored caplet-shaped tablet is debossed with “203” on one side and plain on the other.

INGREDIENTS:

Each tablet of Nicaprin™ contains:

Niacin (nicotinamide)	250 mg
Folic Acid	500 mcg
Vitamin B6 (pyridoxine HCl)	4.5 mg
Copper (cupric oxide)	1.4 mg
Zinc (zinc oxide)	9 mg
Soliprin (scutellaria baicalensis (root) & acacia catechu (heartwood))	125 mg

OTHER INGREDIENTS:

Iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium bicarbonate, starch, silica, talc, and titanium dioxide.

INDICATIONS AND USAGE:

This product is indicated for patients who are deficient in, or at risk of deficiency in, one or more of the components of this product.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS:

This product should be administered with caution in patients with a history of liver disease, jaundice or diabetes mellitus. While prescribing this product for pregnant women, nursing mothers, or for women prior to conception, their medical condition and use of other drugs, herbs and/or supplements should be considered. Folic acid above 1 mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations remain progressive. Abnormal liver functions tests have been reported in persons taking daily doses of 500 mg or more of niacinamide.

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

PREGNANCY & NURSING MOTHERS:

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

ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about side effects. **To report a serious adverse event, call 1-855-899-4237.**

DOSAGE AND ADMINISTRATION:

Usual adult dose is 1 to 2 tablets daily, or as directed by a physician.

HOW SUPPLIED:

This product is supplied in the following size(s):
60 count bottles, **NDC 57893-203-60**

Store between 15°C and 30°C (between 59°F and 86°F). Tamper evident by foil seal under cap.

Manufactured for:
Artesa Labs, LLC
137585 Research Blvd.
Suite 125
Austin, TX 78750
v1 Rev. 05/16 826146

PRINCIPAL DISPLAY PANEL - 60 TABLET BOTTLE LABEL

NDC 57893-203-60

Rx Only

NICAPRIN™

Dietary Supplement

60 Tablets

Artesa Labs

NDC 57893-203-60

Rx only

NICAPRIN™
Dietary Supplement

60 Tablets

Artesa Labs

Supplement Facts

Serving Size: 1 Tablet

	Amount Per Serving
Niacin (nicotinamide)	250 mg
Folic Acid	500 mcg
Vitamin B ₆ (pyridoxine HCl)	4.5 mg
Copper (cupric oxide)	1.4 mg
Zinc (zinc oxide)	9 mg
Soliprin (scutellaria baicalensis (root) & acacia catechu (heartwood))	125 mg

OTHER INGREDIENTS: Iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium bicarbonate, starch, silica, talc, and titanium dioxide.

INDICATIONS AND USAGE: This product is indicated for patients who are deficient in, or at risk of deficiency in, one or more of the components of this product.

DOSAGE AND ADMINISTRATION: Usual adult dose is 1 to 2 tablets daily, or as directed by a physician. Please see package insert for full prescribing information. Store between 15°C and 30°C (between 59°F and 86°F). Tamper evident by foil seal under cap.

Manufactured for: Artesa Labs, LLC, 137585 Research Blvd., Suite 125, Austin, TX 78750
VI Rev. 05/16 826143

**NICAPRIN**

nicotinamide, folic acid, pyridoxine hydrochloride, cupric oxide, zinc oxide, and soliprin tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:57893-203
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	250 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1.4 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	4.5 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SCUTELLARIA BARBATA WHOLE (UNII: DPR4R122E7)	
ACACIA CATECHU WOOD (UNII: CHL342Y4LA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:57893-203-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		09/21/2016	

Supplement Facts**Serving Size :** **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	14 mm	
scoring	1	
imprint		

Labeler - Artesa Labs, LLC (078786339)

Revised: 9/2016

Artesa Labs, LLC