

NICAZYME- nicazyme tablet
Sterling Knight Pharmaceuticals LLC

Nicazyme Tablets
Dietary Supplement

DESCRIPTION:

Nicazyme is an orally administered prescription dietary supplement formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

Nicazyme should be administered under the supervision of a licensed medical practitioner.

INDICATIONS AND USAGE:

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

CONTRAINDICATIONS:

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Nicazyme should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

WARNINGS AND PRECAUTIONS:

This product should be administered with caution in patients with a history of liver disease, jaundice or diabetes mellitus.

Folic acid above 1mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations remain progressive.

Abnormal liver function test have reported in persons takings doses of 500mg or more of naicinamide.

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

ADVERSE REACTION:

Allergic sensitization has been reported following both oral and parental administration of folic acid.

DOSAGE AND ADMINISTRATION:

Usual dose is 1 to 2 tablets daily with or without food. Do not exceed 3 tablets per day.

STORAGE:

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. **KEEP THIS OUT OF THE REACH OF CHILDREN.**

HOW SUPPLIED:

Nicazyme is supplied a beige tablet dispensed in white HDPE plastic bottles of 30ct.

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

KEEP OUT THE REACH OF CHILDREN.

Storage:
Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place.

Manufactured for:
Sterling | Knight Pharmaceuticals, LLC
Ripley, MS 38663

69336-404-30
NICAZYME
CONCENTRATED VITAMIN SUPPORT
DISPENSE BY PRESCRIPTION

3 69336 40430 3
Rev 0419-1 Item: 40430

30 TABLETS DIETARY SUPPLEMENT

SUPPLEMENT FACTS		
Serving Size: 1 tablet		
Servings Per Container: 30		
Amount Per Serving	% Daily Value	
Niacin (as Niacinamide)	250mg	1250%
Folic Acid	500mcg	125%
Vitamin B6 (as Pyridoxine HCL)	4.5mg	225%
Copper (as Cubric)	1.4mg	70%
Zinc (as Zinc Oxide)	9mg	60%
Proprietary Blend	125mg	*
Scutellaria baicalensis (Chinese Skullcap) root extract, Acacia catechu (Heartwood) bark extract		
* Daily values not established		

Other Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Stearic Acid, Silicon Dioxide, Coating (Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, Carmel).
Contains: Wheat

Reserved for Professional Recommendation

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:

Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663

NICAZYME			
nicazyme tablet			
Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69336-404
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	0.5 mg	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	4.5 mg	
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	1.4 mg	
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	9 mg	
Inactive Ingredients			
Ingredient Name	Strength		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-404-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		06/05/2019	

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

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	22 mm	
scoring	1	

Labeler - Sterling Knight Pharmaceuticals LLC (079556942)

Revised: 6/2019

Sterling Knight Pharmaceuticals LLC