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:

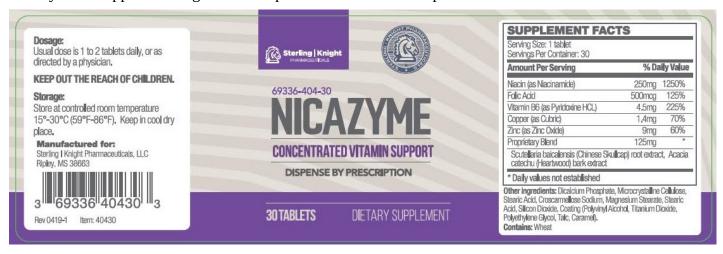
Usual dose is 1 to 2 tablets daily with or without food. Do not exceed 3 tablets per day.

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.



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: 2679 MF687A) (NIACIN - UNII:2679 MF687A)	NIACIN	250 mg	
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.5 mg	
PYRIDO XINE HYDRO CHLO RIDE (UNII: 68 Y4CF58 BV) (PYRIDO XINE - UNII: KV2JZ1BI6Z)	PYRIDO XINE HYDROCHLO RIDE	4.5 mg	
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	1.4 mg	
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	9 mg	

Inactive Ingredients		
Strength		

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