PRODIGEN- lactobacillus acidophilus capsule Sterling Knight Pharmaceuticals LLC

Prodigen Capsules Dietary Supplement

HEALTH CLAIM:

Prodigen Capsules Dietary Supplemement

Dispensed by Prescription†

SUPPLEMENT	Γ FACT	S
Serving Size: 1 capsule Servings Per Container: 30		
Amount Per Serving		% Daily Value
Lactobacillus acidophilus	16 Billion	
Bifidobacterium Animalis lactis	15 Billion	•
* Daily values not established		

Other ingredients: Gelatin, Microcrystalline Cellulose, Magnesium Stearate, Hydrated Silica.

DESCRIPTION

Prodigen is an orally administered prescription probiotic 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.

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

WARNINGS AND PRECAUTIONS

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

Prodigen 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.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 capsule daily with or without food.

INDICATIONS AND USAGE

Prodigen is an orally administered prescription probiotic 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.

HOW SUPPLIED:

Prodigen is supplied as clear capsules dispensed in 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

Item 40230 Rev. 0418-1

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.

PACKAGE LABEL:



PRODIGEN

lactobacillus acidophilus capsule

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69336-402
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)	LACTOBACILLUS ACIDOPHILUS	16000000000 [CFU]
BIFIDOBACTERIUM ANIMALIS LACTIS (UNII: 5307V7XW8I) (BIFIDOBACTERIUM ANIMALIS LACTIS - UNII:5307V7XW8I)	BIFIDOBACTERIUM ANIMALIS LACTIS	15000000000 [CFU]

Inactive Ingredients		
Ingredient Name	Strength	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:69336-402-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/27/2018	

Supplement F	acts	
Serving Size:		Serving per Container :
	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	16 mm	
scoring	1	

Labeler - Sterling Knight Pharmaceuticals LLC (079556942)

Revised: 7/2018 Sterling Knight Pharmaceuticals LLC