PROBITRAN- probiotic capsule PureTek Corporation

Probitran™

STATEMENT OF IDENTITY

Probitran™

Supplement Facts Serving Size: 1 Capsule Servings per container: 30 Amount Per Serving: %DV			
Proprietary Blend Probiotic Bacteria: 2 Strain AcidoBifido Capsule	31 billion CFU	*	
Lactobacillus acidophilus Bifidobacterium animalis lactis			
* Daily Value (DV) not establishe	ed		

Other Ingredients: Potato Starch, Magnesium Stearate, Ascorbic Acid, Vegetable Capsule (Hydroxypropylmethylcellulose).

Probitran™ 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.

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

Probitran™ is manufactured in accordance with Current Good Manufacturing Practice for foods, using ingredients that have been approved by the U.S. Food and Drug Administration (FDA) as food additives or are Generally Recognized as Safe (GRAS) for their intended use.

DOSAGE

Usual Adult dose is one capsule once daily, or as prescribed by a licensed medical practitioner.

If you are pregnant or nursing, ask a healthcare professional.

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

SAFE HANDLING

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

Probitran[™] 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.

KEEP OUT OF REACH OF CHILDREN

STORAGE

Store at 20° to 25°C (68° to 77°F). Keep in a cool dry place.

HOW SUPPLIED HEALTH CLAIM

Probitran™, Probiotic

Dietary Supplement

NHRIC: 59088-183-54 *

Bottles contain 30 Capsules

Manufactured in Canada and Distributed in the USA by: PureTek Corporation

Panorama City, CA 91402 Questions? Call toll-free:

1-877-921-7873

*Does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

† The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

Probitran™

List No: 18354IAA Rev:38306



Supplement Facts

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ANIMALIS LACTIS

Proprietary Blend 31 billion CFU Probiotic Bacteria:

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Bifidobacterium animalis lactis

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PROBITRAN

probiotic capsule

Product Information

Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:59088-183

Route of Administration ORAL

(BIFIDOBACTERIUM ANIMALIS LACTIS - UNII:5307V7XW8I)

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NHRIC:59088-183-54	30 in 1 BOTTLE				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
DIETARY SUPPLEMENT		05/03/2021				

Supplement Facts

Serving Size : Serving per Container :

Amount Per Serving % Daily Value

color

shape size (solid drugs) 25 mm scoring 1

Labeler - PureTek Corporation (785961046)

Revised: 5/2021 PureTek Corporation