

LACTEROL- probiotic capsule
PureTek Corporation

Lacterol™

STATEMENT OF IDENTITY

Lacterol™

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

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

Lacterol™ 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.

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

Lacterol™ 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.

Lacterol™ 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.

Lacterol™ 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

Lacterol™, Probiotic

Dietary Supplement

NHRIC: 59088-179-54 *

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.

Lacterol™

59088-179-54

DERMACINRx[®]**Lacterol™****31**

BILLION

Digestive Probiotic**Multi Strain**
Supports Digestive Balance

DIETARY SUPPLEMENT 30 Capsules

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List No: 17954IAA Rev: 38250

**LACTEROL**

probiotic capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:59088-179
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)	LACTOBACILLUS ACIDOPHILUS	1600000000 [CFU]
BIFIDOBACTERIUM ANIMALIS LACTIS (UNII: 5307V7XW8I) (BIFIDOBACTERIUM ANIMALIS LACTIS - UNII:5307V7XW8I)	BIFIDOBACTERIUM ANIMALIS LACTIS	1500000000 [CFU]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:59088-179-54	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		02/09/2021	

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: 2/2021

PureTek Corporation