NEWFLORA- probiotic capsule Trell Pharma

NewFlora

STATEMENT OF IDENTITY

NewFlora

Other Ingredients: Maltodextrin, Vegetable Capsule.

NewFlora 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.

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

NewFlora 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.

NewFlora 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.

NewFlora 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 2° to 8°C (35° to 46°F). Store in the refrigerator after opening, DO NOT freeze.

HOW SUPPLIED HEALTH CLAIM

NewFlora, Probiotic

Dietary Supplement

NHRIC: 82379-8757-01 *

Bottles contain 30 Capsules

Distributed by: Trell Pharma

Tampa, FL

*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.

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SUPPLEMENT FACTS

Serving Size: 1 Capsule Daily
Servings Per Container: 30

Amt. Per Serving: % DV ‡

Lactobacillus acidophilus 10 Billion
CFUs ‡

† % Daily value not established
Keep refrigerated after opening

Other Ingredients: Maltodextrin &
Vegetable Capsules

Storage: at 2° -8° C (35° -46° F)
[see USP Controlled Room Temperature]
Store in refrigerator after opening, DO NOT freeze

82379 - 8757 - 01

Manufactured in the USA for: Trell Pharmaceuticals

Tampa, FL Questions? Call: 813 - 576 - 1843 82379-8757-01

TRELL

NewFlora

Probiotic

Dietary Supplement | 30 Capsules

NEWFLORA

probiotic capsule

Produc	ct Inf	form	ation
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Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:82379-8757

Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)	LACTOBACILLUS ACIDOPHILUS	1000000000 [CFU]

Inactive Ingredients	
Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:82379-8757-1	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		03/04/2022	

Supplement Facts			
Serving Size :		Serving per Container:	
	Amount Per Serving	% Daily Value	
color			
shape			
size (solid drugs)	24 mm		
scoring	1		

Labeler - Trell Pharma (118380801)

Revised: 3/2022 Trell Pharma