FLORA Q2- lactobacillus acidophilus capsule PharmaDerm A division of Fougera Pharmaceuticals Inc.

Flora•Q[®]2 Double Strength Unique Blend of Probiotic Strains Dietary Supplement Gluten Free BRAND NAME: Flora•O[®]2

PRODUCT DESCRIPTION: Off-white capsules, each containing 300 mg* of a standardized, light-beige colored powder consisting of an aggregate of a minimum of 16 billion CFU (16 x 10⁹ Colony Forming Units) freeze-dried cultures at time of manufacture of species listed below.

Guaranteed potency of no less than 8 billion CFU freeze-dried cultures at expiration date.

* Based on an estimated tapped density of 0.7 g/mL.

Also contains: maltodextrin, hypromellose, microcrystalline cellulose, sodium alginate, silicon dioxide, magnesium stearate, titanium dioxide, and FD&C Blue 2.

Each capsule, containing a proprietary probiotic blend and other ingredients, is equivalent to 375 mg per serving.

This product is free of the following allergens: wheat/gluten, milk/lactose, eggs, fish, crustacean shellfish, soybeans, tree nuts, and peanuts.

Contains no preservatives.

GENERIC NAME:

Lactobacillus acidophilus

Bifidobacterium

Lactobacillus paracasei

Streptococcus thermophilus

COMMON USES: This probiotic is used to help maintain the normal bacterial balance of the gastrointestinal tract.[†]

THE PROBIOTIC SPECIES IN FLORA Q® 2:

- Help maintain balance in the intestinal microflora.[†]
- Support the colonization of intestinal microflora.[†]
- Help support the modulation of intestinal microflora.[†]
- Promote gastrointestinal health.[†]

[†]These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

HOW TO USE: Use this product as directed on the package, unless instructed differently by your doctor.

CAUTIONS: Before you begin taking any dietary supplement, check with your doctor or pharmacist.

KEEP OUT OF THE REACH OF CHILDREN.

POSSIBLE SIDE EFFECTS: Potential side effects that may dissipate include increased stomach gas. If this occurs and is bothersome, check with your doctor. Should you experience symptoms of an

allergic reaction, including rash, itching, swelling, dizziness or trouble breathing, contact your doctor, nurse or pharmacist immediately.

DIRECTIONS: Take one capsule per day. May be taken with or without food.

HOW SUPPLIED: Off-white capsules imprinted **Flora Q**[®] 2 are supplied in bottles of 30 (List 10337-001-30).

STORAGE: Potency guaranteed through expiration date on package when stored at room temperature (25° C/77° F) or below. DO NOT STORE IN THE BATHROOM. Keep container closed. No refrigeration needed.

Do not use if seal on bottle is broken or missing.

Manufactured for:

PharmaDerm®

A divisdion of

Fougera

PHARMEUTICALS INC.

Melville, New York 11747

www.pharmaderm.com

IL306B R11/11

Principal Display Panel – Carton Label

List 10337-001-30

30

Capsules

Double Strength

Flora•Q®2

Unique Blend

of Probiotic Strains

Dietary Supplement

Gluten Free

 $PharmaDerm^{\hbox{\it \'R}}$



Principal Display Panel – Bottle Label

List 10337-001-30

30 Capsules

Double Strength

Flora•Q®2

Unique Blend of Probiotic Strains

Dietary Supplement

Gluten Free

PharmaDerm[®]







Other ingredients: malbdextrin, microcrystaline cellulose, hypromellose, sodium alginate, silcon dioxide, magnesium stearate, titanium dioxide, and FD&C Blue 2.

This product is tree of the following allergens: wheel/gluteo, milk/factose, eggs, fish, crustacean shellfish, soybeans, tree nuts, and peanuts.

Contains no preservatives. IL305B R11/11

Lot No. Exp. Date:

FLORA Q2

lactobacillus acidophilus capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:10337-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength	
	lactobacillus acidophilus (UNII: 1PRR1V42V5) (lactobacillus acidophilus - UNII:1PRR1V42V5)	lacto bacillus acido philus	16000000000 [CFU]	

Inactive Ingredients		
Ingredient Name	Strength	
maltodextrin (UNII: 7CVR7L4A2D)		
hypromelloses (UNII: 3NXW29V3WO)		
cellulose, microcrystalline (UNII: OP1R32D61U)		
sodium alginate (UNII: C269C4G2ZQ)		
silicon dioxide (UNII: ETJ7Z6XBU4)		
magnesium stearate (UNII: 70097M6I30)		
titanium dioxide (UNII: 15FIX9 V2JP)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:10337-001-30	1 in 1 CARTON		
1		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		08/01/2007	

Supplement Fac	cts	
Serving Size :		Serving per Container:
Α	mount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	16 mm	
scoring	2	
imprint		

Labeler - PharmaDerm A division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 5/2012 PharmaDerm A division of Fougera Pharmaceuticals Inc.