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

Flora•Q[®]
Dietary Supplement
Gluten Free

BRAND NAME: Flora•Q®

PRODUCT DESCRIPTION: Off-white capsules, each containing 180 mg* of a standardized, light-beige colored powder consisting of an aggregate of a minimum of 8 billion CFU (8 x 10⁹ Colony Forming Units) freeze-dried cultures at time of manufacture of species listed below.

Guaranteed potency of no less than 4 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 230 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®:

- 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**[®] are supplied in bottles of 30 (List 10337-400-30).

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

IL195B R11/11

Principal Display Panel – Carton Label

List 10337-400-30

30

Capsules

Flora•Q®

Unique Blend

of Probiotic Strains

Dietary Supplement

Gluten Free

Pharma Derm[®]



Principal Display Panel – Bottle Label

List 10337-400-30

30 Capsules

Flora•Q®

Unique Blend of Probiotic Strains

Dietary Supplement

Gluten Free

PharmaDerm[®]



List 10337-400-30

30 Capsules



Unique Blend of Probiotic Strains

Dietary Supplement

Gluten Free



Supplement Facts

Serving Size: 1 Capsule

Amount Per Serving 230 mg % Daily Value

Proprietary Probiotic blend:

Lactobacillus acidophilus Bifidobacterium

Lactobacillus paracasei *
Streptococcus thermophilus *

Daily Value not established

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

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

Contains no preservatives. IL194B R11/11

Exp. Date

FLORA Q

lactobacillus acidophilus capsule

Product Information

Product TypeDIETARY SUPPLEMENTItem Code (Source)NHRIC:10337-400

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength

lactobacillus acidophilus (UNII: 1PRR1V42V5) (lactobacillus acidophilus UNII:1PRR1V42V5)

Basis of Strength

lactobacillus
acidophilus

8000000000 [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: 15FIX9V2JP) FD&C BLUE NO. 2 (UNII: L06K8R7DQK)

Pa	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 1	NHRIC:10337-400-30	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		07/01/2004	

Supplement Facts						
Serving Size :		Serving per Container:				
A	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.