

FLORRAXIS- lactobacillus acidophilus,bifidobacterium animalis lactis tablet
Florrx Pharmaceutical Corp.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Florrxaxis is an orally administered prescription probiotic dietary supplement.

Florrxaxis 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. Should be administered under the supervision of a licensed medical practitioner.

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

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B 12 deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In the case of accidental overdose, call a doctor or poison control center immediately.

Preservative Free and Gluten Free

Allergens: None

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact Florrx Pharmaceuticals at 888-321-2821.

One tablet daily or as directed by a physician.

Modified Cellulose, Silicon Dioxide, Magnesium Stearate.

Bottles of 30 Tablets (84460-602-30). Tablet is light blue, oblong.

*Florrx Pharmaceuticals does not represent this product's code to be National Drug Code (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

This product is a prescription-folate with or without other dietary ingredients - due to increased folate levels increased risk associated with masking B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (64 FR 8760). 1-3 the most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only 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 statues as applicable. The ingredients, indication or claims of this product are not to be construed to be Drug claims.

- 1.) Federal register Notice of August 2, 1973 (39 FR 20750)
- 2.) Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
- 3.) Federal register notice of March 5, 1996 (61 FR 8760)

: Store at 20- 25 degree C (68-77 F) excursions permitted to 15 -30 degree C (59-86 F) {See USP controlled Room Temperature} Avoid excessive heat, light and moisture.

TAMPER EVIDENT: Do not use if seal is broken or missing.

MADE IN USA
Distributed by:
888-321-2821
Florrax Pharmaceutical
Dallas, TX 75161

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

DOSAGE AND ADMINISTRATION:
Usual adult dosage is 1 tablet taken orally once daily or as prescribed by a licensed medical practitioner.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.** In case of accidental overdose, call a doctor or poison control center immediately.

STORAGE: Store at 20°-25°C (68°-77°F) excursions permitted to 15°-30°C(59°-86°F)[- See UPS Controlled Room Temperature] Aviod excessive heat, light and moisture.

84460-602-30

Florraxis™

PROBIOTIC SUPPORT

Lactobacillus Acidophilus
Bifidobacterium Animalis Lactis
31 Billion CFU'


30 CAPSULES

DIETARY SUPPLEMENT



Dispensed by Prescription

See package outsert for full prescribing information



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Florrax Pharmaceuticals
Dallas, TX 75161
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FLORRAXIS

lactobacillus acidophilus,bifidobacterium animalis lactis tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84460-602
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)		LACTOBACILLUS ACIDOPHILUS	16000000000 [CFU]
BIFIDOBACTERIUM ANIMALIS LACTIS (UNII: 5307V7XW8I) (BIFIDOBACTERIUM ANIMALIS LACTIS - UNII:5307V7XW8I)		BIFIDOBACTERIUM ANIMALIS LACTIS	15000000000 [CFU]

Product Characteristics

Color	blue (light blue)	Score	no score
Shape	OVAL	Size	23mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84460-602-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/12/2024	

Labeler - Florrax Pharmaceutical Corp. (119257612)

Revised: 12/2024

Florrax Pharmaceutical Corp.