

**FLORRAXYL- beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopherol acetate, pyridoxine hci, biotin, folate, cyanocobalamin, calcium carbonate, magnesium oxide, ferrochel™, potassium iodide tablet**  
**Florrax Pharmaceutical**

*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.*

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**Florraxyl**

Florraxyl is a prescription multivitamin/multimineral dietary supplement.

Florraxyl is a prescription multivitamin/multimineral dietary supplement formulated for the clinical dietary management of a suboptimal nutritional status in patients where advanced folate, vitamin B supplementation, and maintenance of good health is needed.

Florraxyl 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.

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 Florrax Pharmaceuticals at 888-321-2821.

One tablet daily or as directed by a physician.

Bottles of 30 Tablets (84460-903-30). Tablet is light blue, oblong.

\*Florrax Pharmaceuticals does not represent this product 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 B 12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (64 FR 87 60). 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 statutes 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)

STORAGE: 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  
Florrx 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] Avoid excessive heat, light and moisture.

84460-903-30

**Florraxyl™**


**DIETARY SUPPLEMENT**

**30 TABLETS**



Dispensed by Prescription

See package outsert for full prescribing information



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Florrx Pharmaceuticals  
Dallas, TX 75161  
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FLORRAXYL

beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopherol acetate, pyridoxine hci, biotin, folate, cyanocobalamin, calcium carbonate, magnesium oxide, ferrochel™, potassium iodide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84460-903
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.67 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	4.5 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	80 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	0.15 mg

<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)		ASCORBIC ACID	60 mg	
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)		BETA CAROTENE	300 ug	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)		PYRIDOXINE	26 mg	
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)		CYANOCOBALAMIN	0.013 mg	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)		CHOLECALCIFEROL	10 ug	
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)		BIOTIN	0.28 mg	
<b>FERROUS BISGLYCINATE</b> (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)		FERROUS CATION	20 mg	
<b>Product Characteristics</b>				
<b>Color</b>	blue	<b>Score</b>	no score	
<b>Shape</b>	OVAL	<b>Size</b>	12mm	
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:84460-903-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2025	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other			01/01/2025	

**Labeler** - Florrax Pharmaceutical (119257612)

Revised: 1/2025

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