VITACORE- multivitamin tablet Florrax 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.

Vitacore is a prescription multivitamin/multimineral dietary supplement.

Vaticore is a prescription multivitamin/multi-mineral dietary supplement formulated for the clinical dietary management of a subuoptimal nutritional status in patients where advanced folate, vitamin B supplementation, and maintenance of good health is needed.

Vaticore 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. Felic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNING Accidental overdose of iron-containing products is a leading cause of fatal poising 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 reports 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 (84460-901-30). Tablet is light blue, oblong.

*Florrax Pharmaceuticals does not represent this products code to be National Drug Code

(NDC). Products codes are formatted according to standard industry practice, to meet the

formatting requirement by pedigree reporting and supply-chain control including pharmacies.

This products is a prescription-folate with or without other dietary ingredients the - 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) Storage and Handing

STORAGE: Store at 20- 25 degree C (68-77 F) excersions 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



84460-902-30 Multivitamin Dietary Supplement Dispensed by Prescription

DESCRIPTION

Vitacore is a prescription multivitamin/multimineral dietary supplement.

Serving size Amount per serving:		ablet Navy Kale
Wtamin A (as Beta-Carotone)	300 mcg RAE	339
Vitamin C (as Ascorbic Acid)	60 mg	67%
Vitamin D (as Cholecalciferol)	10 mcg	509
Vitamin E (as d-Alpha Tocopherol Acetale)	4.5 mg (10 IU)	339
Wtamin B6 (as Pyridoxine HCI)	26 mg	15299
Botin	0.290 mg	9339
Folate	1.67 mg DFE	4189
(from Folic Acid)	0.67 mg DFE	
(from 5-Methyl Tetrahydrofolate, Calcium	n Salt)	
	1 mg DFE	
Witamin B12 (as Cyanocobalamin)		
	0.013mg	5429
Calcium (as Calcium Carbonate)	80 mg	69
Magnesium (as Magnesium (hide)	25 mg	69
Ferroche/TM**	20 mg	111 mg
ladine (as Patassium ladide)	0.150 mg	1009

OTHER INGREDIENTS: Microcrystalline Cellulose, Maltodextrin, Croscarmellose Socium, ISSilicon Dioxide, Stearic Acid, Magnesium Stearate, Film Coating (Hydroxpropos)/Mikhthylcallulose, Polyethylene Glycol, Titanium Dioxide, FD&C Blue # 1)

Allergen: NONE

Indications: Vaticore is a prescription multivitamin/multimineral dietary supplement formulated for the clinical dietary management of a subuoptimal nutritional status in patients where advanced folate, vitamin B supplementa-tion, and maintenance of good health is needed.

Contraindications: Vaticore is contraindicated in patients with a known hypersensitivity to any of the ingredients.

Precautions: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNING Accidental overdose of iron-containing products is a leading cause of fatal poising 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.

ADVERSE REACTIONS 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 reports adverse side effects or to obtain product information, contact Florrax Pharmaceuticals at 888-321-2821.

DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

HOW SUPPLIED

Bottles of 30 Tablets (84460-901-30). Tablet is light blue, oblong.

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KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

These statement have not been evaluated by the Food and Drugs Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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VITACORE

multivitamin tablet

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:84460-902 Route of Administration ORAL

Active Ingredient/Active Moiety

Ingred	lient	Name
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FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	0.15 mg
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	0.3 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.1 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	26 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.28 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.67 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	0.013 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	80 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:70WA1RIO01)	.ALPHA TOCOPHEROL, DL-	4.5 mg

Inactive Ingredients		
Ingredient Name	Strength	
STEARIC ACID (UNII: 4ELV7Z65AP)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code		
Contains				

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:84460-902-	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2025		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2025	
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