

FLORRAVITE- multivitamin 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.

Description

Florrvite is a prescription multivitamin/multimineral dietary supplement.

Other Ingredients

Microcrystalline Cellulose, Maltodextrin, Croscarmellose Sodium,® Silicon Dioxide, Stearic Acid, Magnesium Stearate, Film Coating (Hydroxypropyl® Methylcellulose, Polyethylene Glycol, titanium Dioxide, FD&C Blue# 1)

Indications

Florrvite 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.

Contraindications

Florrvite 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 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.

ALLERGIES: NONE

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 report adverse side effects or to obtain product information, contact Florrx Pharmaceuticals at 800-000-0000.

Dosage & Administration

One tablet daily or as directed by a physician.

How Supplied

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 & Handling

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
Florrax Pharmaceutical Corp.
Terrell TX 75161

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

Package Label

84460-901-30

Florravite™

DIETARY SUPPLEMENT

30 TABLETS

Dispensed by Prescription

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 USP Controlled Room Temperature] Avoid excessive heat, light and moisture.

See package insert for full prescribing information



Distributed by:
Florrax Pharmaceuticals
Terrell, TX 75161
888-321-2821
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FLORRAVITE

multivitamin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84460-901
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	1.15 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	0.28 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	1 mg
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	4.5 mg
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	300 ug
MAGNESIUM OXIDE (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	25 mg
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	26 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	0.013 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	80 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.67 mg

Product Characteristics

Color	blue (light blue)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84460-901-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2024	

Labeler - Florrax Pharmaceutical Corp. (119257612)

Revised: 7/2024

Florrax Pharmaceutical Corp.