PROFOLA- beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, pyridoxine hydrochloride, biotin, folic acid, levomefolate calcium, cyanocobalamin, calcium carbonate, magnesium oxide, ferrous bisglycinate, and potassium iodide tablet
Redmont Pharmaceuticals, LLC

ProFola
71741-141-30
Multivitamin Dietary Supplement

Dispensed by Prescription

DESCRIPTION

ProFola is a prescription multivitamin/multimineral dietary supplement.

Supplement Facts **Serving size 1 Tablet**		
Amount per Serving:		**%Daily Value**
Vitamin A (as Beta-Carotene)	300 mcg RAE	33%
Vitamin C (as Ascorbic Acid)	60 mg	67%
Vitamin D (as Cholecalciferol)	10 mcg	50%
Vitamin E (as dl-Alpha Tocopherol Acetate)	4.5 mg (10 IU)	33%
Vitamin B6 (as Pyridoxine HCl)	26 mg	1529%
Biotin	0.280 mg	933%
Folate	1.67 mg DFE	418%
(from Folic Acid)	0.67 mg DFE	*
(from 5-Methyl Tetrahydrofolate, Calcium Salt)	1 mg DFE	*
Vitamin B12 (as Cyanocobalamin)	0.013 mg	542%
Calcium (as Calcium Carbonate)	80 mg	6%
Magnesium (as Magnesium Oxide)	25 mg	6%
Ferrochel™ Iron (as Ferrous BisGlycinate Chelate)	20 mg	111%

Iodine (as Potassium Iodide)	0.150 mg	100%

* Daily Value not established

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)

Allergen: NONE

INDICATIONS

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

CONTRAINDICATIONS

ProFola 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 is 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 report adverse side effects or to obtain product information, contact Redmont Pharmaceuticals, LLC at 1-800-986-5909.

DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

HOW SUPPLIED

Bottles of 30 tablets (71741-141-30[1]). Tablet is light blue, oblong.

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1 Redmont Pharmaceuticals does not represent this product 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 that – 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 (38 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 HANDLING

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.

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

MADE IN USA

Distributed by:

Redmont Pharmaceuticals, LLC
Birmingham, AL 35209
800-986-5909

Ferrochel™ is a trademark of Albion Laboratories, Inc.

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.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

141111-0721

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

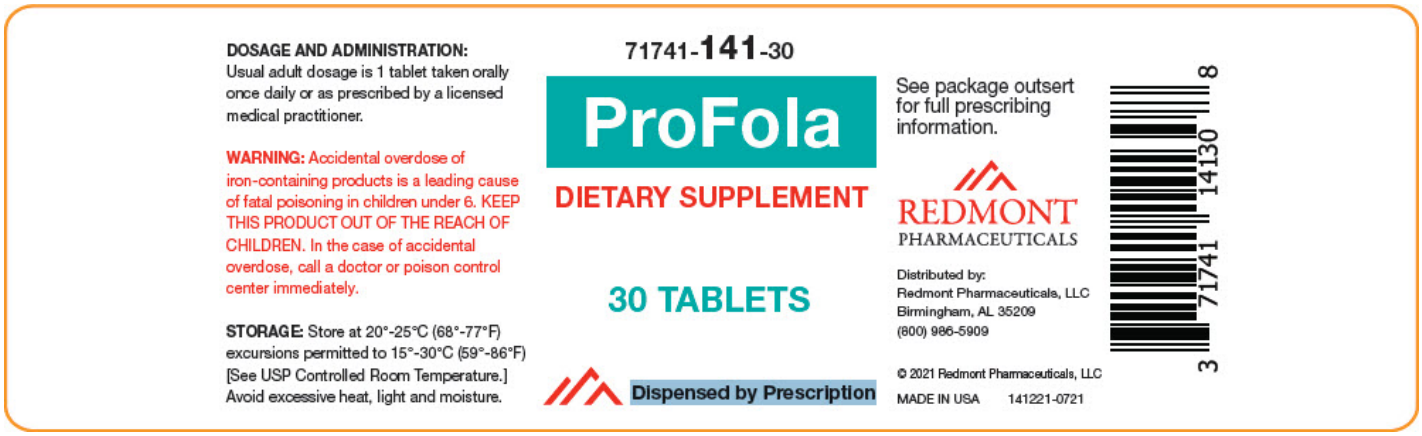
71741-141-30

ProFola

DIETARY SUPPLEMENT

30 TABLETS

Dispensed by Prescription



PROFOLA

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, pyridoxine hydrochloride, biotin, folic acid, levomefolate calcium, cyanocobalamin, calcium carbonate, magnesium oxide, ferrous bisglycinate, and potassium iodide tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:71741-141
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Beta Carotene (UNII: 01YAE03M7J) (Beta Carotene - UNII:01YAE03M7J)	Beta Carotene	300 ug
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	10 ug
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol Acetate	4.5 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	26 mg
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	0.28 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.4 mg
Levomefolate Calcium (UNII: A9R10K3F2F) (Levomefolic Acid - UNII:8S95DH25XC)	Levomefolate Calcium	0.6 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	0.013 mg
Calcium Carbonate (UNII: H0G9379FGK) (Calcium Cation - UNII:2M83C4R6ZB)	Calcium Carbonate	80 mg
Magnesium Oxide (UNII: 3A3U0GI71G) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Oxide	25 mg
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

Inactive Ingredients

Ingredient Name	Strength
Microcrystalline Cellulose 102 (UNII: PNR0YF693Y)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Magnesium Palmitostearate (UNII: R4OXA9G5BV)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71741-141-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		08/09/2021	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	19 mm	

Labeler - Redmont Pharmaceuticals, LLC (080843607)

Revised: 8/2021 Redmont Pharmaceuticals, LLC