

**FOLIKA-MG- beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, cobalamin, biotin, calcium carbonate, ferrous bisglycinate, potassium iodide, magnesium oxide capsule**  
**Innovida Pharmaceutique Corporation**

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## **Innovida FOLIKA-MG**

### **Dosage and Administration**

Adults should take one (1) tablet daily, preferably with a meal or as recommended by a physician.

### **WARNING**

**Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control central immediately.**

Folika-MG tablets should only be used under the direction and supervision of a licensed medical practitioner. This product is contraindicated in patients with known hypersensitivity to any of the ingredients. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

### **PRECAUTION**

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B is deficient. Folic acid in doses above 1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Folika-MG Tablets should only be used under the direction and supervision of a licensed medical practitioner.

### **ADVERSE REACTIONS**

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling 304-303-5399 or the FDA by calling 1-800-FDA-1088.

### **KEEP OUT OF THE REACH OF CHILDREN.**

**Tamper Evident:** Do not use if seal is broken or missing.

### **HEALTH CLAIM:**

Folika-MG Tablets

Dietary Supplement

### **DESCRIPTION:**

Folika-MG Tablets is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed, such as throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. Folika-MG Tablets may be useful in improving the nutritional status of woman prior to conception.

### **HOW SUPPLIED:**

Folika-MG Tablets are supplied 30 tables in a child resistant bottle.

\*Innovida Pharmaceutique Corporation does not represent these product codes to be National Drug Codes (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 of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 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 (Rx). 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 (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:

Store at 20°-25°C (66°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Protect from heat, light and moisture

Dietary Supplement

## Product Label

71800-810-30

**Suggested Use:** As a dietary supplement, adults take one (1) tablet daily preferably with a meal or as recommended by a physician.

**KEEP OUT OF REACH OF CHILDREN**

**STORAGE:** Store product at room temperature. Do not expose to excessive heat or moisture.

Vitamin C tends to change color with age; this does not affect potency.

**WARNING:** Accidental overdose of iron containing products is 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.



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**INNVIDA**  
PHARMACEUTIQUE CORPORATION

**FOLIKA-MG**  
Dietary Supplement

**Supplement Facts**

Serving size: 1 tablet  
Serving per container: 30

	Amount per serving	% Daily Value
Vitamin A (as beta-carotene)	300 mcg	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	30%
Vitamin B6 (as pyridoxine HCl)	25 mg	1329%
Folate	1570 mcg DFE	418%
from (5-methyltetrahydrofolate calcium salt)	1000 mcg DFE	
from (as folic acid)	670 mcg DFE	
Vitamin B12 (as cyanocobalamin)	13 mcg	543%
Biotin	280 mcg	933%
Calcium (as calcium carbonate)	80 mg	6%
Iron (ferrous fumarate as ferrous bisglycinate chelate)	20 mg	111%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	25 mg	6%

Daily Value not established

Other Ingredients: Lactitol, Phosphorus, Modified Cellulose Gum, Vegetable Stearates, Sodium Citrate, Silicon Dioxide, Dark Orange Film Coating: Polyvinyl Alcohol, Polyethylene Glycol, FD&C Yellow #5 Lake (tartrazine), FD&C Yellow #6 Lake, Titanium Dioxide

Manufactured for: Innovida Pharmaceutical Corporation  
Charleston, WV 25301

LOT:

EXP:

**30 tablets**

## FOLIKA-MG

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, cobalamin, biotin, calcium carbonate, ferrous bisglycinate, potassium iodide, magnesium oxide capsule

### Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRC:71800-810
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	0.3 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	0.06 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.01 mg
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	4.5 mg

<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	26 mg		
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.67 mg		
<b>COBALAMIN</b> (UNII: 8406EY2OQA) (COBALAMIN - UNII:8406EY2OQA)	COBALAMIN	0.013 mg		
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.013 mg		
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	80 mg		
<b>FERROUS BISGLYCINATE</b> (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg		
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	0.150 mg		
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg		
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)				
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71800-810-30	30 in 1 BOTTLE		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
dietary supplement			06/16/2020	

<b>Supplement Facts</b>	
<b>Serving Size :</b>	<b>Serving per Container :</b>
<b>Amount Per Serving</b>	<b>% Daily Value</b>
shape	
scoring	1
color	
size (solid drugs)	19 mm

