IRON FOLATE-F- iron folate-f capsule Westminster Pharmaceuticals, LLC

Iron Folate-F with Ascorbic Acid Precursors

Supplement Facts Serving Size: 1 Capsule Servings Per Container: 90				
	Amount Per Serving	% DV for Adults and Children over 12	% DV for Pregnant and Lactating Women	
Vitamin C (Ascorbic Acid)*	40 mg	44%	33%	
Niacin (as Niacinamide Ascorbate)	3 mg NE	19%	17%	
Folate	1667 mcg DFE (1000 mcg folic acid)	417%	278%	
Iron (from Ferrous Fumarate and Polysaccharide Iron Complex)	125 mg	694%	463%	

^{*} Also containing Ascorbic Acid Precursors as (1) Acid Metabolites including niacinamide ascorbate, calcium ascorbate, magnesium ascorbate, potassium ascorbate, and sodium ascorbate; (2) Basic Amino Acids including lysine acetate; (3) Flavonoids including hesperidin complex, and (4) Glutathione.

Other Ingredients: Hydroxypropyl Methyl Cellulose, Microcrystalline Cellulose, Silicon Dioxide, Magnesium Stearate, Titanium Dioxide, FD&C Red #40, FD&C Blue #1

Iron Folate-F is a professionally prescribed iron, folic acid, and vitamin supplement used to improve the nutritional status of patients with iron and/or folate deficiency anemia, including women in the prenatal and postnatal period. **Do not administer to children under the age of 12.**

CONTRAINDICATIONS

Iron Folate-F is contraindicated in patients with a known hypersensitivity to any of the ingredients, also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindicated, as folic

acid may obscure its signs and symptoms.

WARNINGS

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.

PRECAUTIONS

General

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where B12 is deficient. Anemia requires appropriate investigation to determine its cause or causes. Periodic clinical and laboratory studies are considered essential. Blood tests including hemoglobin and hematocrit should be done to determine the adequacy of therapy. Folic acid should be used with care in the presence of peptic ulcer disease, regional enteritis, and ulcerative colitis. In doses above 0.1 mg daily, folic acid may obscure the diagnosis of pernicious anemia.

USAGE IN PREGNANCY

Before Iron Folate-F is prescribed for megaloblastic anemia in pregnancy, appropriate diagnostic exclusion of Addisonian pernicious anemia (due to faulty or blocked absorption of vitamin B12, or extrinsic factor or either a genetic, immunological or surgical basis) should be carried out.

Pediatric Use

Safety and effectiveness of this product have not been established in pediatric patients.

Geriatric Use

Safety and effectiveness of this product have not been established in elderly patients.

ADVERSE REACTIONS

Folic Acid

Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.

Ferrous Fumarate

Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation, heartburn, and vomiting) occur occasionally, but are usually mild and may subside with continuation of therapy. Reducing the dose and administering it with meals will minimize these effects in the sensitive patient. Iron may turn stools black. This is a harmless effect that is a result

of unabsorbed iron. Although the absorption of iron is best when taken between meals, giving Iron Folate-F after meals may diminish occasional G.I. disturbances. Iron Folate-F is best absorbed when taken at bedtime.

OVERDOSAGE

Acute overdosage of iron may cause abdominal pain, nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other more chronic symptoms include pallor and cyanosis, melena, shock, drowsiness, and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. Toxic effects are seen at 10-20 mg/kg elemental iron. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Iron Folate-F should be stored beyond the reach of children to prevent against accidental iron poisoning.

DESCRIPTION

Iron Folate-F are maroon capsules imprinted "217" in white.

DIRECTIONS FOR USE

One (1) capsule daily, between meals, or as directed by a physician. Do not exceed recommended dosage.

HOW SUPPLIED

Iron Folate-F is supplied in bottles of 90 capsules (69367-217-09) and 30 capsules (69367-217-30).

STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP with a child-resistant closure.

KEEP OUT OF THE REACH OF CHILDREN.

For use on the order of a healthcare practitioner.

To report a serious adverse event contact 1-844-221-7294

Manufactured for:

Westminster Pharmaceuticals, LLC Nashville, TN 37217 Rev. 06/23

PRINCIPAL DISPLAY PANEL - 90 Capsule Bottle Label

69367-217-09

Iron Folate-F with Ascorbic Acid Precursors

IRON / FOLIC ACID / VITAMIN DIETARY SUPPLEMENT

90 Capsules

Westminster **Pharmaceuticals**



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\$10RAGE: Store at 20°-28°C (68°-77°P), excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature). Dispense in a tight, light-resistant container as defined in the USP with a child-resistant closure. For use on the order of a healthcare practitioner. KEEP OUT OF THE REACH OF CHILDREN.

To report a serious adverse event contact 1-844-221-7294 Manufactured for:
Weshiniser Pramazeuticals, LLC
Recovile, TN 37217
Rev 06/23

IRON FOLATE-F

iron folate-f capsule

Product Information				
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69367-217	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	62.5 mg		
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	62.5 mg		
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg		
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	40 mg		
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	3 mg		

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69367-217-30	30 in 1 BOTTLE		
2	NHRIC:69367-217-09	90 in 1 BOTTLE		

Marketing Information					
Marketing Category					
DIETARY SUPPLEMENT		07/19/2023			

Supplement Facts				
Serving Size :		Serving per Container :		
	Amount Per Serving	% Daily Value		
color				
scoring	1			
shape				
size (solid drugs)	22 mm			
imprint				

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2023