

IRON FOLATE PLUS- iron folate plus capsule
Westminster Pharmaceuticals, LLC

Iron Folate Plus

Supplement Facts		
Serving Size: 1 Capsule		
Servings Per Container: 90		
	Amount Per Serving	% DV for Adults and Children over 12
Vitamin C (Ascorbic Acid)*	210 mg	233%
Thiamin (as Thiamine Mononitrate)	5 mg	417%
Riboflavin	5 mg	385%
Niacin	20 mg NE	125%
Vitamin B6 (as Pyridoxine HCl)	25 mg	1471%
Folate	1667 mcg DFE (1000 mcg folic acid)	417%
Vitamin B12 (as Cyanocobalamin)	10 mcg	417%
Biotin	300 mcg	1000%
Pantothenic Acid (as D-Calcium Pantothenate)	7 mg	140%
Iron (from Ferrous Fumarate and Polysaccharide Iron Complex)	125 mg	694%

* Also containing Ascorbic Acid Precursors as (1) Acid Metabolites including, 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 Yellow #5

Iron Folate Plus is a prescription multivitamin nutritional supplement indicated for improving nutritional status in adults with certainty illnesses or vitamin deficiencies. **DO NOT ADMINISTER TO CHILDREN UNDER THE AGE OF 12.**

CONTRAINDICATIONS

Iron Folate Plus is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis,

hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

WARNINGS

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.

PRECAUTIONS

General

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia assessment, such that hematologic remission can occur while neurological manifestations remain progressive.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

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.

DRUG INTERACTIONS

Iron Folate Plus is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g. Aspirin, Heparin, Clopidogrel).

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) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, taking Iron Folate Plus after meals may diminish occasional G.I. disturbances. Iron Folate Plus 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 Plus should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this product out of the reach of children.

Treatment

For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

DESCRIPTION

Iron Folate Plus are yellow capsules imprinted "218" in black.

DIRECTIONS FOR USE

Adults and children over 12 years of age: One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage.

HOW SUPPLIED

Iron Folate Plus is dispensed in child-resistant bottles of 90 Capsules (69367-218-09) and 30 Capsules (69367-218-30).

STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

KEEP OUT OF 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

69367-218-09

Rx

Iron Folate
Plus

with Ascorbic Acid Precursors

IRON / FOLIC ACID / VITAMIN
DIETARY SUPPLEMENT

90 Capsules

Westminster
Pharmaceuticals

69367-218-09
Rx

Iron Folate Plus

with Ascorbic Acid Precursors

**IRON / FOLIC ACID / VITAMIN
DIETARY SUPPLEMENT**

90 Capsules

WP Westminster
Pharmaceuticals

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 90

Amount Per Serving	% DV for Adults and Children over 12
Vitamin C (Ascorbic Acid)*	210 mg 233%
Thiamin (as Thiamine Mononitrate)	5 mg 417%
Riboflavin	5 mg 385%
Niacin	20 mg NE 125%
Vitamin B6 (as Pyridoxine HCl)	25 mg 1471%
Folate (1000 mcg folic acid)	1667 mcg DFE 417%
Vitamin B12 (as Cyanocobalamin)	10 mcg 417%
Biotin	300 mcg 1000%
Pantothenic Acid (as D-Calcium Panthothenate)	7 mg 140%
Iron (from Ferrous Fumarate and Polysaccharide Iron Complex)	125 mg 694%

*Also containing Ascorbic Acid Precursors as (1) Acid Metabolites including, 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 Yellow #5


DIRECTIONS FOR USE: Adults and children over 12 years of age: One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage.

STORAGE: Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

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.

KEEP OUT OF THE REACH OF CHILDREN.

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37211 Rev. 06/23



69367 121809 1 2

Peel for prescribing information

Iron Folate Plus is a prescription multivitamin nutritional supplement indicated for improving nutritional status in adults with certain illnesses or vitamin deficiencies. **DO NOT ADMINISTER TO CHILDREN UNDER THE AGE OF 12.**

CONTRAINDICATIONS: Iron Folate Plus is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemochromatosis, hemochromatosis, or hemolytic anemia. Ferric chloride is a contraindication, as folic acid may obscure its signs and symptoms.

WARNINGS:

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.

PRECAUTIONS:

General: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia assessment, such that hematologic remission can occur while neurological manifestations remain progressive.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, leading to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

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

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

DRUG INTERACTIONS:

Iron Folate Plus is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Coumadin).

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) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, taking Iron Folate Plus after meals may diminish occasional GI disturbances. Iron Folate Plus is best absorbed when taken at bedtime.

OVERDOSE AGE: Acute overdose 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 Plus should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this product out of the reach of children.

Treatment: For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

DESCRIPTION: Iron Folate Plus are yellow capsules imprinted "218" in black.

DIRECTIONS FOR USE: Adults and children over 12 years of age: One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage.

HOW SUPPLIED: Iron Folate Plus is dispensed in child-resistant bottles of 90 Capsules (69367-218-09) and 30 Capsules (69367-218-30).

STORAGE: Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

KEEP OUT OF REACH OF CHILDREN.

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

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37211
Rev. 06/23

IRON FOLATE PLUS

iron folate plus capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69367-218
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	62.5 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	62.5 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	210 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	5 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	300 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 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 YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69367-218-30	30 in 1 BOTTLE		
2	NHRIC:69367-218-09	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		07/19/2023	

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	24 mm	
imprint		

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2023

Westminster Pharmaceuticals, LLC