

PUREVIT DUALFE PLUS- ferrous fumarate, polysaccharide iron complex capsule
PureTek Corporation

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.

PureVit DualFe Plus

CLINICAL PHARMACOLOGY:

PureVit DualFe Plus is unique in that it utilizes two different forms of iron, i.e., Ferrous Fumarate and Polysaccharide Iron Complex (as cell-contracted akaganeite), making available a total of 106 mg of elemental iron per capsule as follows:

Ferrous Fumarate (anhydrous) 162 mg

Polysaccharide Iron Complex (PIC) 115.2 mg

Subclinical B-Group vitamin deficiencies have greatly increased in recent years due to changes in dietetic habits, increase in the use of sugar, and the excessive milling of flour and cereals. With thiamine deficiencies so prevalent in a healthy populace, it is self-evident that the unwell person is particularly prone to thiamine avitaminosis. This is true of the anemic individual with his or her poor appetite and disturbed digestive functions. Folic acid is best known for its role in megaloblastic anemias. Zinc has been recognized in the nutrition of animals and humans, even though the evidence for an uncomplicated zinc deficiency in humans is limited.

Ferrous Fumarate: Provides about 53 mg of elemental iron per dose. Ferrous Fumarate is an anhydrous salt of a combination of ferrous iron and fumaric acid, containing 33% of iron per weight. The acute toxicity in experimental animals is low and Ferrous Fumarate is well tolerated clinically. As a ferrous salt, it is more efficiently absorbed in the duodenum. Ferrous Fumarate contrasts very favorably with the availability of the 20% of elemental iron of ferrous sulfate, and the 13% of elemental iron of ferrous gluconate.

Polysaccharide Iron Complex: Provides about 53 mg of elemental iron, as a cell-contracted akaganeite. It is a product of ferric iron complexed to a low molecular weight polysaccharide. This polysaccharide is produced by extensive hydrolysis of starch and is a dark brown powder that dissolves in water to form a very dark brown solution, which is virtually odorless and tasteless.

Folic Acid:

Folic Acid is one of the most important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Folic acid is a precursor

to a large family of compounds which serve as coenzymes in carbon transfer reactions. These reactions are required for the synthesis of purine and pyrimidine bases, inter-conversion of glycine and serine, biosynthesis of methionine methyl groups and degradation of histidine. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.

INDICATIONS:

PureVit DualFe Plus is indicated for the treatment of iron deficiency anemia and folate deficiency as in extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss and advanced age. Also for treatment of condition in which iron deficiency and vitamin C deficiency occur together, along with a deficient intake or increased need for B-Complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in convalescence.

CONTRAINDICATIONS:

PureVit DualFe 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.

WARNING:

Accidental overdose of Iron-containing products is the leading cause of fatal poisoning of children under 6. **Keep this product out of reach of children.** In case of accidental overdose, call a doctor or Poison Control Center immediately.

Folic acid alone is improper therapy in the treatment for pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient.

PRECAUTIONS:

General: Folic Acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations, remain progressive.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:

No clinical studies have been performed in patients age 65 and over to determine whether older patients respond differently from younger patients. Dosage should always begin at the low end of the dosage scale and should consider that elderly patients may have decreased hepatic, renal or cardiac function, and of concomitant diseases.

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, giving **PureVit DualFe Plus** after meals may control occasional gastrointestinal disturbances. **PureVit DualFe Plus** is best absorbed when taken at bedtime.

Call your doctor for medical advice about side effects. You may report suspected side effects to the FDA at 1-800-FDA-1088.

OVERDOSE:

Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. **PureVit DualFe Plus** should be stored beyond the reach of children to prevent against accidental iron poisoning. **Keep this and all other drugs out of 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.

DOSAGE AND ADMINISTRATION:

Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

HOW SUPPLIED:

PureVit DualFe Plus are yellow capsules imprinted horizontally "P-112", bottles of 90 capsules NDC 59088-112-66. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Keep in a cool, dry place.

Label

Supplement Facts

Serving Size: 1 Capsule

	Amount Per Serving	% Daily Value
Vitamin C (as sodium ascorbate)	200 mg	330%
Vitamin B ₁ (as thiamine mononitrate)	10 mg	667%
Vitamin B ₂ (riboflavin)	6 mg	353%
Vitamin B ₃ (as niacinamide)	30 mg	150%
Vitamin B ₆ (as pyridoxine hydrochloride)	5 mg	250%
Folic Acid	1000 mcg	250%
Vitamin B ₁₂ (as cyanocobalamin)	15 mcg	250%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%
Iron, elemental	106 mg	588%
Derived from:		
Ferrous Fumarate (anhydrous)	152 mg	
Polysaccharide Iron Complex	115.2 mg	
Zinc (as zinc sulfate)	18.2 mg	121%
Copper (as cupric sulfate)	0.8 mg	40%
Manganese (as manganese sulfate)	1.3 mg	66%

Other Ingredients: Silicon Dioxide, Magnesium Stearate, Gelatin, Titanium Dioxide, FD&C Yellow #5, FD&C Yellow #6, SB-6018 Blue Ink.
Contains NO artificial flavors or preservatives, yeast, wheat, gluten, nuts, soy or milk-based by-products.

Consult package insert for full prescribing information.

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.

INDICATIONS: PureVit DualFe Plus is indicated for the treatment of iron deficiency anemia and folate deficiency as in extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss and advanced age.

Also for treatment of condition in which iron deficiency and vitamin C deficiency occur together, along with a deficient intake or increased need for B-Complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in convalescence.

DOSE AND ADMINISTRATION: Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.



NDC 59088-112-66

Rx Only

PureVit DualFe Plus

Ferrous Fumarate/Polysaccharide Iron Vitamin-Mineral Complex Capsules

Store at controlled room temperature 15° to 30° C (59° to 86° F).
Keep in a cool, dry place.

Mfd. By: PureTek Corporation
San Fernando, CA 91340

PharmaPure Rx

90 CAPSULES Dietary Supplement

PUREVIT DUALFE PLUS

ferrous fumarate, polysaccharide iron complex capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	0.8 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	53 mg
IRON DEXTRAN (UNII: 95HR524N2M) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	53 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	6 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	30 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	10 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	200 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	10 mg
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18.2 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	1.3 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	yellow	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	P112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-112-66	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2011	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-112) , pack(59088-112) , label(59088-112)

Revised: 1/2023

PureTek Corporation