

SE-TAN PLUS- multivitamin/mineral capsule, gelatin coated
Seton Pharmaceuticals

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.

Se-Tan PLUS

Ferrous Fumarate / Polysaccharide Iron Complex / Multivitamin Mineral Capsules

R_x Only

DESCRIPTION: Se-Tan PLUS are white capsules imprinted in black "T503". Each capsule contains:

Supplement Facts

Servings per Bottle: 90 Serving Size: 1 capsule Each Capsule contains:	%DV for Adults	
Iron (as ferrous fumarate anhydrous)	32.5 mg	181%
Polysaccharide Iron Complex	115.2 mg	642%
Vitamin C (Sodium Ascorbate)	200 mg	222%
Vitamin B ₁ (Thiamine Mononitrate)	10 mg	833%
Vitamin B ₂ (Riboflavin)	6 mg	462%
Vitamin B ₆ (Pyridoxine HCl)	5 mg	294%
Vitamin B ₁₂ (Cyanocobalamin Concentrate)	15 mcg	250%
Folate (folic acid)	1000 mcg	250%
Niacinamide	30 mg	188%
Pantothenic Acid (as Calcium Pantothenate)	10 mg	200%
Zinc (as Zinc Sulfate)	18.2 mg	165%
Manganese (as Manganese Sulfate)	1.3 mg	57%
Copper (as Copper Sulfate)	0.8 mg	89%

OTHER INGREDIENTS

FD&C Blue #1, FD&C Red #40, FD&C Yellow #6, Gelatine, Magnesium Stearate, Microcrystalline Cellulose, Silica, Titanium Dioxide.

CLINICAL PHARMACOLOGY

Oral iron is absorbed most efficiently when administered between meals. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport, energy production and proper function of cells. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes, which are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is the

precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Deficiency of folic acid may account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic macrocytic anemias. Vitamin B₁₂ is essential to growth, cell reproduction, hematopoiesis, nucleic acid, and myelin synthesis. Deficiency may result in megaloblastic anemia or pernicious anemia.

INDICATIONS AND USAGE:

Se-Tan 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:

Se-Tan PLUS is contraindicated in patients with a 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: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient.

WARNING: Accidental overdose of iron-containing products is the leading cause of fatal poisoning in children under six. Keep this and all drugs out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

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 of this product have not been established in pediatric patients.

Geriatric Use: No clinical studies have been performed in patients age 65 and over to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function and or 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 Se-Tan PLUS after meals may control occasional G.I. disturbances. Se-Tan PLUS is best absorbed when taken at bedtime.

DRUG INTERACTIONS

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

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. Se-Tan PLUS should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this and all other drugs 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.

DOSAGE AND ADMINISTRATION:

Adults (persons over 12 years of age), one (1) capsule daily, orally, 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:

Se-Tan PLUS are white capsules imprinted in black "T503". Child resistant bottles of 90 capsules.

Product Code: NDC 13925-118-90.

PHARMACIST:

Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Storage:

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP controlled room temperature]. Keep in a cool dry place.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Rx Only

RESERVED FOR PROFESSIONAL RECOMMENDATION.

Manufactured for:

Seton Pharmaceuticals
Manasquan, NJ 08736
1-800-510-3401

MADE IN CANADA

Code 118-90 Rev.03/18

SETON PHARMACEUTICALS

PRINCIPAL DISPLAY PANEL

NDC 13925-118-90

Se-Tan-PLUS

**Ferrous Fumarate / Polysaccharide Iron Complex /
Multivitamin Mineral Capsules**

90 Capsules

Rx Only

SETON PHARMACEUTICALS

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Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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MADE IN CANADA L100195 Rev. 03/18

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13925-118
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	162 mg
IRON DEXTRAN (UNII: 95HR524N2M) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	115.2 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	200 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	10 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	6 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	5 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	30 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	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
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	0.8 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	T503
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13925-118-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2009	

Labeler - Seton Pharmaceuticals (828898002)

Registrant - Seton Pharmaceuticals (828898002)

Revised: 5/2022

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