

Customer: Rainbow Gold Products Inc.

Date: 08/31/10

Product Name: Se-Tan Plus Capsules Outsert

Part#: _____

Folded size: 1.125" x 1.125"



Flat sheet size: 8.938" x 5.563"

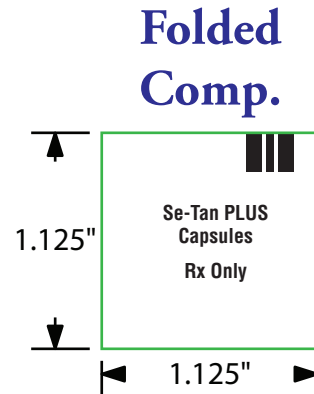
of panels: 40

Paper used: 27# Pharmopaque

Rev.: **2**

Customer Comments/Instructions: _____

PMS Colors Used Front						
						
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Please indicate status below.
Please sign, date, and return if approved.

REVISE AND RE-PROOF APPROVED

APPROVAL SIGNATURE _____

DATE: _____

Front

5.563"

8.938"

Se-Tan PLUS

Ferrous Fumarate / Polysaccharide Iron Complex / Multivitamin Mineral Capsules

Rx Only

DESCRIPTION: Each capsule contains:

Ferrous Fumarate (anhydrous)	162 mg
Polysaccharide Iron Complex	115.2 mg
(Equivalent to about 106 mg of elemental iron)	
Vitamin C (Sodium Ascorbate)	200 mg
Vitamin B₁ (Thiamine Mononitrate)	10 mg
Vitamin B₂ (Riboflavin)	6 mg
Vitamin B₆ (Pyridoxine HCl)	5 mg
Vitamin B₁₂ (Cyanocobalamin Concentrate)	15 mcg
Folic Acid	1 mg
Niacinamide	30 mg
Pantothenic Acid (as Calcium Pantothenate)	10 mg
Zinc (as Zinc Sulfate)	18.2 mg
Manganese (as Manganese Sulfate)	1.3 mg
Copper (as Copper Sulfate)	0.8 mg

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

INDICATIONS: 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: 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.

WARNING: Folic acid alone is improper therapy in the treatment of 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 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.

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.

NDC 13925-118-90.

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

Storage: Store at controlled room temperature 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

Rev. 09/10



Rx Only
Capsules
Se-Tan PLUS



Se-Tan PLUS
Capsules
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