

### **PRODUCT** 51991-543-90 Multigen™ Caplets

**BRECKENRIDGE** 

PRODUCT

†Vitamin C

Ascorbic Acid (as Calcium Ascorbate) ....150 mg Threonic Acid (as Calcium Threonate) ......2 mg Vitamin B<sub>12</sub> (as Cyanocobalamin) ......10 mcg Elemental Iron (as Sumalate®\*) ......70 mg Succinic Acid......75 mg Desiccated Stomach Substance ......50 mg

**EACH CAPLET** 

**CONTAINS** 

Beige, film-coated caplet, debossed B543 SI7F

90

**DETAILED** 

**DESCRIPTION** 



## IMPORTANT FACTS ABOUT MULTIGEN™. MULTIGEN™ PLUS AND MULTIGEN™ FOLIC CAPLETS

Multigen™, Multigen™ Plus and Multigen™ Folic contain the same active ingredients as Chromagen® Forte and Chromagen® FA Tablets, formerly marketed by Ther-Rx Corporation, Sumalate® is a unique patent-protected iron formulation of Ferrous Asparto Glycinate, Sumalate® is a registered trademark of Albion Laboratories and is protected under U.S. Patent Nos. 5.516.925; 6.716.814; 8.007.846. Other U.S. patents pending.

See Product Information on back for more information regarding Medical Foods.

For more information on these products or to take advantage of our sampling program, give us a call or visit us at www.bpirx.com.



Breckenridge Pharmaceutical, Inc.

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Sumalate® is a registered trademark of Albion Laboratories and is protected under U.S. Patent Nos. 5.516,925; 6.716,814; 8.007,846, Other U.S. patents pending. © 2011 Breckenridge Pharmaceutical, Inc. All rights reserved.

### Multigen™ Caplets Medical Food

Each Multigen™ Caplet contains: †Vitamin C

Vitamin B<sub>12</sub> (as Cyanocobalamin)
Elemental fron (as Sumalate®\*) 10 mcg 70 mg Desiccated Stomach Substance TVitamin C is provided as a blend of Calcium Ascorbate and Calcium

Other ingredients:

Microcrystalline Cellulose, Dicalcium Phosphate, Croscarmellose Sodium, Stearic Acid, Crospovidone, Hypromellose, Citric Acid, Soy Polysaccharide, Magnesium Silicate, Titanium Dioxide, Triacetin, Sodium Lauryl Sulfate, Silica, Mineral Oli, Magnesium Stearate, Polyvinyfyrrolidone and Caramel

### Allergen: Contains Soy.

"Sumalate" (Ferrous Asparto Glycinate) is a registered trademark of Albion International, Inc., Clearfield, Utah and is licensed exclusively to Breckenridge Pharmaceutical, Inc., for certain iron products. INDICATIONS AND USAGE:

For the dietary management of individuals with distinct nutritional needs for anemias responsive to oral iron supplementation, such as hypochromic anemia associated with pregnancy, chronic or acute blood loss, dietary restriction, metabolic disease and post-surgical convalescence. Multigen<sup>TM</sup> is labeled as a medical food intended for use under the active and ongoing

# medical supervision requiring medical care on a recurring basis for, among other things, instructions on the use of the medical food.

Medical Foods are intended for the dietary management of a patient who because of therapeutic or chronic medical needs, has limited or impaired

capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by modification of the normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

#### CONTRAINDICATIONS:

Multigen™ Caplets are contraindicated in patients with a known hypersensitivity to any of the ingredients. All iron compounds are contraindicated in patients with hemochromatosis and hemosiderosis.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

#### PRECAUTIONS:

General: Do not exceed recommended dosage.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or

Pediatric Use: Safety and effectiveness in the pediatric population have not been established.

Geriatric Use: Clinical studies on this product have not been performed in subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

### ADVERSE REACTIONS:

Adverse reactions with iron supplementation may include constipation, diarrhea, nausea, vomiting, dark stools and abdominal pain. Adverse reactions with iron therapy are usually transient.

### DOSAGE AND ADMINISTRATION: Usual adult dosage is 1 caplet daily, or as directed by a physician or health-

Phone (800) 367-3395

care provider. HOW SUPPLIED:

# Multigen™ Caplets are available as a film-coated beige, capsule-shap tablet, debossed "8543", Supplied in bottles of 90 caplets, 51991-543-90. Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from light and moisture. Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

Do not use this product if the inner safety seal under the cap is torn, broken or missing

### Medical Food

To report a serious adverse event contact: 1-800-367-3395.

Manufactured by: Contract Pharmacal Cor Hauppauge, NY 11788 USA Distributed by: Breckenridge Pharmaceutical, Inc. Boca Raton, FL 33487

## \*U.S. Patent Nos. 5,516,925; 6,716,814; 8,007,846. Other U.S. patents pending.

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