MultigenTM Plus and MultigenTM And MultigenTM Folic Caplets



PRODUCT NUMBER	BRECKENRIDGE PRODUCT	EACH CAPLET CONTAINS	DETAILED DESCRIPTION	SIZE
51991-543-90	Multigen™ Caplets	†Vitamin C Ascorbic Acid (as Calcium Ascorbate)150 mg Threonic Acid (as Calcium Threonate)2 mg Vitamin B ₁₂ (as Cyanocobalamin)10 mcg Elemental Iron (as Sumalate®*)70 mg Succinic Acid	Beige, film-coated caplet, debossed B543	90
51991-544-90	Multigen™ Plus Caplets	Vitamin C Ascorbic Acid (as Calcium Ascorbate)60 mg Threonic Acid (as Calcium Threonate)0.8 mg Folic Acid, USP	Brown, film-coated caplet, debossed B544	90
51991-546-90	Multigen™ Folic Caplets	Vitamin C Ascorbic Acid (as Calcium Ascorbate)150 mg Threonic Acid (as Calcium Threonate)2 mg Folic Acid, USP	Beige, film-coated caplet, debossed B546	90

IMPORTANT FACTS ABOUT MULTIGEN™, MULTIGEN™ PLUS AND MULTIGEN™ FOLIC CAPLETS

Multigen[™], Multigen[™] Plus and Multigen[™] Folic contain the same active ingredients as **Chromagen®**, **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. Boca Raton, FL 33487 www.bpirx.com

Phone (800) 367-3395 Fax (866) 372-7479 email: info@bpirx.com

Multigen™ Caplets **Medical Food**

Each Multigen™ Caplet contains:

†Vitamin C

Ascorbic Acid (as Calcium Ascorbate)	
Threonic Acid (as Calcium Threonate)	2 mg
Vitamin B ₁₂ (as Cyanocobalamin)	10 mcg
Vitamin B ₁₂ (as Cyanocobalamin)Élemental fron (as Sumalate®*)	70 mã
Succinic Acid	75 mg
Desiccated Stomach Substance	50 ma
TVitamin C is provided as a blend of Calcium Ascorb	ate and Calcium
Threonate	

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

"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. MultigenTM is labeled as a medical food intended for use under the active and ongoing medical supervision requiring medical acre on a recurring basis for, among other things, instructions on the use of the medical glood.

Medical Foods:

Other ingredients:

Polyvinylpyrrolidone.

Allergen: Contains Sov.

INDICATIONS AND USAGE:

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

Fach Multigen** Plus Capier contains:

Vitamin C

Ascorbic Acid (as Calcium Ascorbate) 60 mg
Threonic Acid (as Calcium Threonate) 0.8 mg
Folic Acid (USP) 1 mg
Vitamin B₁₂ (as Cyanocobalamin) 10 mcg
Elemental Iron (as "Sumalate") 50 mg
Elemental Iron (as "Sumalate") 50 mg
Elemental Iron (as Ferrous Fumarate) 101 mg
Succinic Acid 50 mg
"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.

Microcrystalline Cellulose, Dicalcium Phosphate, Stearic Acid, Croscarmellose Sodium, Crospovidone, Hypromellose, Citric Acid, Soy Polysaccharide, Sodium Lauryl Sulfate, Magnesium Silicate, Silica, FD&C Yellow No. 6 Lake**, Titanium Dioxide, Triacetin, Magnesium Stearate, Mineral Oil, FD&C Red No. 40 Lake, FD&C Blue No. 1 Lake, and Palvaind-procilidae.

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. MultigenTM Plus 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 the modification of the normal diet alone. Although a medical-food product is

**This product contains Yellow No. 6 Lake as a color additive.

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 the modification of the normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

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 $^{\text{TM}}$ 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.

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 continuing.

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

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-

care provider

HOW SUPPLIED: Multigen™ Caplets are available as a film-coated beige, capsule-shaped tablet, debossed "B543". Supplied in bottles of 90 caplets, 51991-543-90.

Store at 26°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/MF.

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 Corp. 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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Multigen™ Plus Caplets Each Multigen™ Plus Caplet contains:

Medical Food

intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

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.

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. All iron compounds are contraindicated in patients with hemochromatosis and hemosiderosis.

WARNINGS:

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.

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient. PRECAUTIONS:

General: Do not exceed recommended dosage.

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

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

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.

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION:

Usual adult dosage is 1 to 2 caplets daily, or as directed by a physician or health-care provider.

HOW SUPPLIED:

Multigen TM Plus Caplets are available as a brown, film-coated caplet, debossed B 544 in bottles of 90 caplets, 51991-544-90.

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.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN Medical Food

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

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

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

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Each Multigen™ Folic Caplet contains:

Vitamin C	
Ascorbic Acid (as Calcium Ascorbate)	150 mg
Threonic Acid (as Calcium Threonate)	2 mg
Folic Acid, USP	1 mg
Vitamin B ₁₂ (Cyanocobalamin)	10 mcg
Elemental Tron (as †Sumalate®)	70 mg
Succinic Acid	75 ma

Other ingredients: Microcrystalline Cellulose, Dicalcium Phosphate, Croscarmellose Sodium, Hypromellose, Stearic Acid, Crospovidone, Titanium Dioxide, Magnesium Silicate, Sodium Lauryl Sulfate, Silica, Triacetin, Magnesium Stearate, Polyvinylpyrrojidone, Mineral Oil, FD&C Yellow No. 5 Lake* and FD&C Yellow No. 6 Lake**

- Contains FD&C Yellow No. 5 Lake (Tartrazine) as a color additive (see **PRECAUTIONS**).
- Contains FD&C Yellow No. 6 Lake as a color additive.
- † 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 of anemias responsive to oral iron supplementation, such as hypochromic anemia associated with prepanery, chronic or acute blood loss, dietary restriction, metabolic disease and post-surgical convalescence. Multigen¹⁴ Folic 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:

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 the modification of the normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a rescribition. not require a prescription.

Multigen™ Folic Caplets

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:

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. All iron compounds are contraindicated in patients any of the ingredients. All Iron compound with hemochromatosis and hemosiderosis.

WARNINGS

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.

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin ${\rm B}_{12}$ is deficient. PRECAUTIONS

General: Do not exceed recommended dose.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

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

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 supplementation are usually transient.

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION:

Usual adult dosage is 1 caplet daily, or as directed by a physician or health-

HOW SUPPLIED

Multigen™ Folic Caplets are available as a beige, film-coated caplet debossed "B 546". Supplied in bottles of 90 caplets, 51991-546-90.

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.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Medical Food

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

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

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