

CHROMAGEN- ferrous asparto glycinate, ferrous fumarate, ascorbic acid, folic acid, cyanocobalamin, zinc, and intrinsic factor capsule
Avion Pharmaceuticals, LLC

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.

Iron Supplement

Chromagen™

Rx Only Dietary Supplement

DESCRIPTION: Chromagen for oral administration is an iron supplement softgel that is pearlescent dark blue and embossed with CH75 on one side.

| Supplement Facts | | |
|---|--------------------|---------------|
| Serving Size: 1 Softgel | | |
| Servings Per Container: 30 | | |
| | Amount Per Serving | % Daily Value |
| Calories | 10 | |
| Total Fat | 0.5 g | <1%* |
| Saturated Fat | 0 g | 0%* |
| Trans Fat | 0 g | 1 |
| Vitamin C (as ascorbic acid) | 60 mg | 67% |
| Folate (as 1.4 mg Quatrefolic® (6S)-5, methyltetrahydrofolic acid calcium salt (equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg) | 1700 mcg DFE | 425% |
| Vitamin B ₁₂ (as cyanocobalamin) | 10 mcg | 417% |
| Iron (as Sumalate® (ferrous asparto glycinate 25 mg) and ferrous fumarate 50 mg) | 75 mg | 425% |
| Zinc (as zinc bisglycinate chelate) | 12 mg | 109% |
| Dessicated Stomach Substance | 100 mg | 1 |
| * Percent Daily Values (DV) are based on a 2,000 calorie diet 1 Daily Value not established | | |

OTHER INGREDIENTS: Beeswax, soybean oil and soy lecithin. Gelatin capsule (bovine gelatin, Candurin® Blue Shimmer (mica-based pearlescent pigment), caramel coloring,

carob, glycerin, FD&C Blue #1, purified water).

INDICATIONS: Chromagen™ is a multivitamin/multimineral dietary supplement indicated for use in improving the nutritional status of patients with iron deficiency.

CONTRAINDICATIONS: Chromagen™ is contraindicated in patients with a known hypersensitivity to any of the ingredients.

PRECAUTIONS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNING: 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.

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

WARNING: Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

DOSAGE AND ADMINISTRATION: One softgel daily, or as directed by a physician.

HOW SUPPLIED: Bottles of 30 softgels (75854-320-30). The listed product number is not a National Drug Code. Instead, Avion Pharmaceuticals has assigned a product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

STORAGE: Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature.]

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

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.

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

MANUFACTURED FOR:

Avion Pharmaceuticals, LLC
Alpharetta, GA 30005 1-888-61-AVION
L-0203 Rev. 0325-02

Quatrefolic® is a registered trademark of Gnosis, SpA. Covered by one or more claims of U.S. Patent # 7,947,662
CAS# 1181972-37-1

Sumalate® is a registered trademark of Albion Laboratories, Inc., covered by one or more claims of U.S. Patent Nos. 6,716,814,8,007,846 and 8,425, 956.

75854-320-30

SUGAR FREE

LACTOSE FREE

Rx Only

Dietary Supplement

Chromagen™

30 softgels

CHROMAGEN

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Sumalige® is a registered trademark of Albion Laboratories, Inc. covered by one or more claims of U.S. Patent Nos. 6,716,814, 8,007,846 and 8,465,866.

www.chromagenrx.com



Rx Only Dietary Supplement

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| Total Fat | 0.5g | <1% |
| Saturated Fat | 0g | 0% |
| Total Iron | 0g | † |
| Vitamin C (as ascorbic acid) | 60 mg | 67% |
| Folate (as L-lysine methyltetrahydrofolate calcium salt) (equivalent to 750 mcg of folic acid) and folic acid (USP 250 mcg) | 1700 mcg (IE, 425%) | |
| Vitamin B12 (as cyanocobalamin) | 10 mcg | 417% |
| Iron (as Sumalige® (ferrous asparto glycinate 25 mg) and ferrous fumarate 50 mg) | 75 mg | 425% |
| Zinc (as zinc bisglycinate chelate) | 12 mg | 100% |
| † Dehydrated Stomach Substance | 100 mg | † |

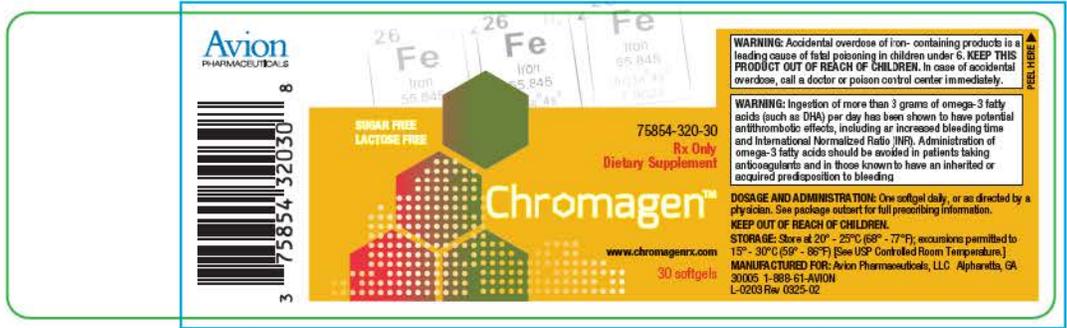
* Percent Daily Values (DV) are based on a 2,000 calorie diet
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OTHER INGREDIENTS: Beeswax, soybean oil and soy lecithin, Gelatin capsule (bovine gelatin, Candurin® Blue Summer (mica-based pearlescent pigment), caramel coloring, carob, glycerin, FD&C Blue #1, purified water).

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Avion PHARMACEUTICALS

75854-320-30
Rx Only
Dietary Supplement

Chromagen™

www.chromagenrx.com
30 softgels

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DOSAGE AND ADMINISTRATION: One softgel daily, or as directed by a physician. See package insert for full prescribing information.

KEEP OUT OF REACH OF CHILDREN.

STORAGE: Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature].

MANUFACTURED FOR: Avion Pharmaceuticals, LLC, Alpharetta, GA 30005 1-888-61-AVION L-0203 Rev. 0325-02

ferrous asparto glycinate, ferrous fumarate, ascorbic acid, folic acid, cyanocobalamin, zinc, and intrinsic factor capsule

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:75854-320 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| FERROUS ASPARTO GLYCINATE (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION | 25 mg |
| FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION | 50 mg |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 60 mg |
| LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC) | LEVOMEFOLIC ACID | 750 ug |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 250 ug |
| CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 10 ug |
| ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS) | ZINC | 12 mg |
| INTRINSIC FACTOR (UNII: 70BT6OQT2Q) (INTRINSIC FACTOR - UNII:70BT6OQT2Q) | INTRINSIC FACTOR | 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SOYBEAN OIL (UNII: 241ATL177A) | |
| GELATIN TYPE B BOVINE (200 BLOOM) (UNII: A7JR5F8DLH) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |
| CAROB (UNII: 5MG5Z946UO) | |
| CARAMEL (UNII: T9D99G2B1R) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |

Product Characteristics

| | | | |
|-----------------|------------------------------|---------------------|----------|
| Color | blue (pearlescent dark blue) | Score | no score |
| Shape | CAPSULE | Size | 22mm |
| Flavor | | Imprint Code | CH75 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:75854-320-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 01/23/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 01/10/2017 | |

Labeler - Avion Pharmaceuticals, LLC (040348516)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Avion Pharmaceuticals, LLC | | 040348516 | manufacture(75854-320) |

Revised: 4/2025

Avion Pharmaceuticals, LLC