

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 TM

Rx Only Dietary Supplement

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DESCRIPTION: ChromagenTM for oral administration is a prenatal/postnatal iron supplement softgel that is pearlescent dark blue and embossed with "CH75" on one side.

Supplement Facts		
Serving Size: 1 softgel		
Amount per Serving:		% Daily Value
Iron (as Sumalate [®] (ferrous asparto glycinate 25 mg) and ferrous fumarate 50 mg)	75 mg	417%
Vitamin C (as ascorbic acid)	60 mg	100%
Folate (as 1.4 mg Quatrefolic [®] (6S)-5, methyltetrahydrofolate glucosamine salt (equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg)	1 mg	250%
Vitamin B12 (as cyanocobalamin)	10 mcg	167%
Zinc (as zinc bisglycinate chelate)	12 mg	80%
Dessicated Stomach Substance	100 mg	†
† Daily Value (DV) not established		

OTHER INGREDIENTS: Gelatin capsule (bovine gelatin, Candurin[®] Blue Shimmer (mica-based pearlescent pigment), carob [St. John's Bread and Caramel], FD&C Blue #1, glycerin, purified water), soybean oil, soy lecithin and beeswax.

INDICATIONS:ChromagenTM 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.

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.

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.

MANUFACTURED FOR:

Avion Pharmaceuticals, LLC

Alpharetta, GA 30005 1-888-61-AVION

Rev. 0519-02 AV-426

THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR INTENDED TO DIAGNOSE, PREVENT ANY DISEASE.

75854-320-30

SUGAR FREE

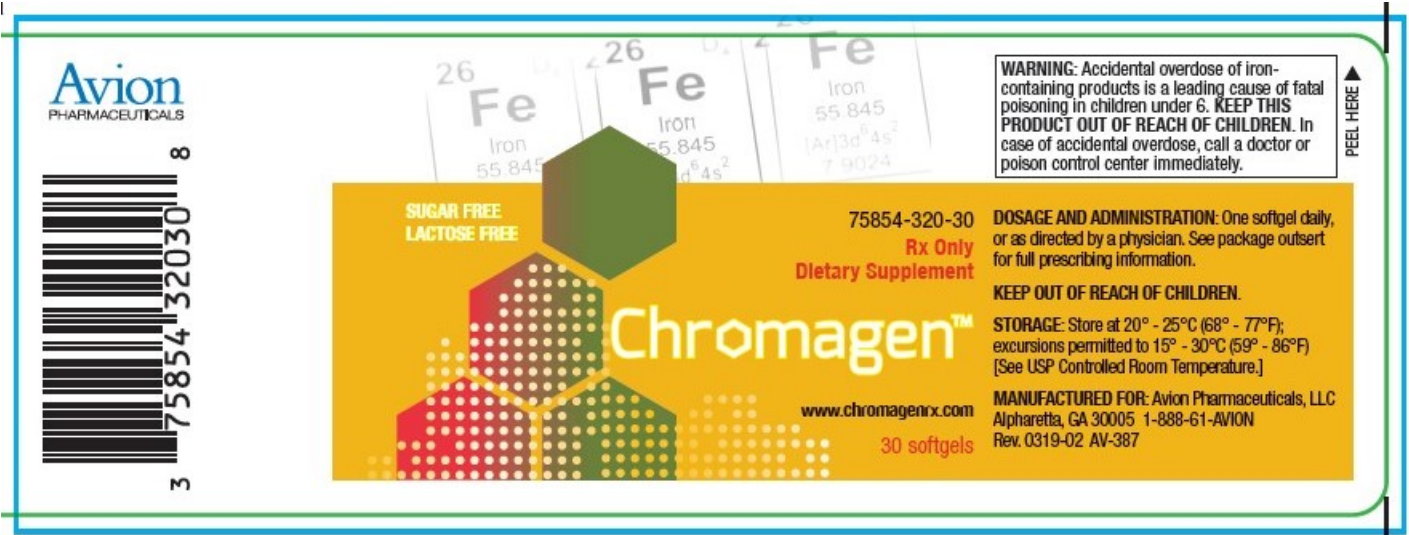
LACTOSE FREE

Rx Only

Dietary Supplement

Chromagen™

30 softgels



CHROMAGEN

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:GW895810WR)	FERROUS CATION	25 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	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: HBR47K3TBD)	
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: 7/2019

Avion Pharmaceuticals, LLC