NIFEREX- ferrous asparto glycinate, iron, ascorbic acid, folic acid, cyanocobalamin, zinc, and succinic acid tablet
Avion Pharmaceuticals, LLC

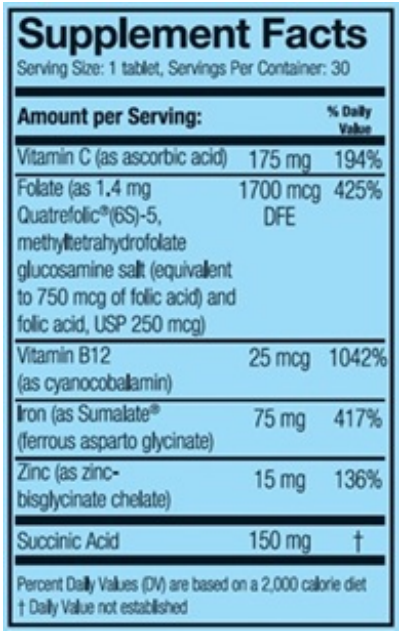
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Iron Supplement

Niferex® Tablets

Rx Only Dietary Supplement

DESCRIPTION: Niferex® for oral administration is an iron supplement that is an oval, copper colored, coated tablet with "344" embossed on one side.



Supplement Facts

Serving Size: 1 tablet, Servings Per Container: 30

Amount per Serving:		% Daily Value
Vitamin C (as ascorbic acid)	175 mg	194%
Folate (as 1.4 mg Quatrefolic®(6S)-5, methyltetrahydrofolate glucosamine salt (equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg)	1700 mcg DFE	425%
Vitamin B12 (as cyanocobalamin)	25 mcg	1042%
Iron (as Sumalate® (ferrous asparto glycinate)	75 mg	417%
Zinc (as zinc-bisglycinate chelate)	15 mg	136%
Succinic Acid	150 mg	†

Percent Daily Values (DV) are based on a 2,000 calorie diet
† Daily Value not established

OTHER INGREDIENTS: Discalcium phosphate dihydrate, microcrystalline cellulose, croscarmellose sodium, stearic acid, silicon dioxide, magnesium stearate. Coating contains: Candurin® Orange (FD&C Blue #1, FD&C Red #40, FD&C Yellow #6), HPMC, titanium dioxide and triacetin.

This product contains FD&C Yellow #6.

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

CONTRAINDICATIONS: Niferex® 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 tablet daily, or as directed by a physician.

HOW SUPPLIED: Bottles of 30 tablets (75854-344-30). 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.]

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.

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

MANUFACTURED FOR:

Avion Pharmaceuticals, LLC

Alpharetta, GA 30005 1-888-61-AVION

L-0437 Rev. 0924-01

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.

75854-344-30

Rx Only Dietary Supplement

30 Tablets

Sugar Free

Lactose Free

Niferex® Tablets (ferrous asparto glycinate)

www.niferex.com

NIFEREX

ferrous asparto glycinate, iron, ascorbic acid, folic acid, cyanocobalamin, zinc, and succinic acid tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75854-344
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	75 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	175 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	750 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	250 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	25 mg
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 mg

SUCCINIC ACID (UNII: AB6MNQ6J6L) (SUCCINIC ACID - UNII:AB6MNQ6J6L)	SUCCINIC ACID	150 mg
INTRINSIC FACTOR (UNII: 70BT6OQT2Q) (INTRINSIC FACTOR - UNII:70BT6OQT2Q)	INTRINSIC FACTOR	100 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	brown (copper colored)	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-344-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/16/2024	

Labeler - Avion Pharmaceuticals, LLC (040348516)

Registrant - Avion Pharmaceuticals, LLC (965450542)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-344)