

**NIFEREX- ferrous asparto glycinate, iron, ascorbic acid, folic acid, cyanocobalamin, zinc, succinic acid, and intrinsic factor 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.*

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**Iron Supplement**

**Niferex<sup>™</sup> Tablets**

**Rx Only Dietary Supplement**

**Rx Only Dietary Supplement**

**DESCRIPTION:** Niferex<sup>™</sup> for oral administration is a prenatal/postnatal iron supplement that is a round, copper colored tablet with "NxFE" embossed on one side.

<b>Supplement Facts</b>		
Serving Size: 1 tablet		
<b>Amount per Serving:</b>		<b>% Daily Value</b>
Iron (as Sumalate <sup>®</sup> (ferrous asparto glycinate 50 mg) and polysaccharide iron complex 100 mg)	150 mg	833%
Vitamin C (as ascorbic acid)	60 mg	100%
Folate (as 1.4 mg Quatrefolic <sup>®</sup> ((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)	25 mcg	417%
Zinc (as zinc-bisglycinate chelate)	15 mg	100%
Succinic Acid	50 mg	†
Dessicated Stomach Substance	100 mg	†
† Daily Value (DV) not established		

**OTHER INGREDIENTS:** Croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid. Coating contains: HPMC, triacetin, titanium dioxide, Candurin<sup>®</sup> Orange (FD&C Blue #1, FD&C Red #40, FD&C Yellow #6). **This product contains FD&C Yellow #6.**

**INDICATIONS:** Niferex<sup>™</sup> 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 softgel daily, or as directed by a physician.

**HOW SUPPLIED:** Bottles of 30 tablets (75854-321-30). 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. 0119-01 AV-428

**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.**

**ⓂRx Only Dietary Supplement 75854-321-30**

30 Tablets **Sugar Free**

**Lactose Free**

**Niferex Ⓜ™**

**www.niferexrx.com tablets**

Supplement Facts	Rx Only Dietary Supplement	75854-321-30	DOSAGE AND ADMINISTRATION: One tablet daily, or as directed by a physician. See package insert for full prescribing information.
Serving Size: 1 Tablet	30 Tablets	SUGAR FREE LACTOSE FREE	<b>KEEP OUT OF REACH OF CHILDREN.</b> <b>STORAGE:</b> Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature.]
Amount per Serving:			<b>MANUFACTURED FOR:</b> Avion Pharmaceuticals, LLC Alpharetta, GA 30005 1-888-61-AMON Rev. 1218-02 AV-384
Iron (as Succinate) and polysaccharide iron complex 100 mg			<b>WARNING:</b> Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. <b>KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.</b> In case of accidental overdose, call a doctor or poison control center immediately.
Iron (as Succinate) and polysaccharide iron complex 100 mg			
Vitamin C (as ascorbic acid) 60 mg			
Folate (as 1.4 mg Quinacrine (6-S)-5, methyltetrahydrofolate calcium salt equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg			
Vitamin B12 (as cyanocobalamin) 25 mcg			
Zinc (as zinc-bisglycinate chelate) 15 mg			
Succinic Acid 50 mg			
Disassociated Stomach Substance 100 mg			
†Daily value (DV) not established			
<p><b>OTHER INGREDIENTS:</b> Croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid. Coating contains: HPMC, triacetin, titanium dioxide, Candurin® Orange (FD&amp;C Blue #1, FD&amp;C Red #40, FD&amp;C Yellow #6). <b>This product contains FD&amp;C Yellow #6.</b></p> <p><b>Niferex™</b> tablets</p> <p>Ferrous asparto glycinate and polysaccharide iron complex</p> <p>Avion PHARMACEUTICALS</p> <p>www.niferex.com</p> <p>3 75854 32130 5</p>			

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## NIFEREX

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

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75854-321
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	50 mg
IRON DEXTRAN (UNII: 95HR524N2M) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	100 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	25 ug
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 mg
SUCCINIC ACID (UNII: AB6MNQ6J6L) (SUCCINIC ACID - UNII:AB6MNQ6J6L)	SUCCINIC ACID	50 mg
INTRINSIC FACTOR (UNII: 70BT6OQT2Q) (INTRINSIC FACTOR - UNII:70BT6OQT2Q)	INTRINSIC FACTOR	100 mg

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

**Product Characteristics**

<b>Color</b>	brown (copper colored)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	NxFE
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-321-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2017	

**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)**Registrant** - Avion Pharmaceuticals, LLC (965450542)**Establishment**

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-321)

Revised: 7/2019

Avion Pharmaceuticals, LLC