

**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>TM</sup> Tablets**  
**Rx Only Dietary Supplement**

**DESCRIPTION:** Niferex 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® (ferrous asparto glycinate 50 mg) 150 mg and polysaccharide iron complex 100 mg)	150 mg	833%
Vitamin C (as ascorbic acid)	60 mg	100%
Folate (as 1.4 mg Quatrefolic® ((6S)-5, methyltetrahydrofolate glucosamine salt molar 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	†
Desiccated Stomach Substance	100 mg	†
† Daily Value (DV) not established		

**OTHER INGREDIENTS:** Dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, vegetable stearate, silicon dioxide.

**INDICATIONS:**

Niferex<sup>TM</sup> is a multivitamin/multimineral dietary supplement indicated for use in improving the nutritional status of patients with iron deficiency.

**CONTRAINDICATIONS:** Niferex<sup>TM</sup> 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:** Before, during and/or after pregnancy, one tablet 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 30022 1-888-61-AVION  
 Rev. 1016-05 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.**

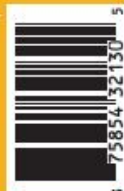
☐Rx Only Dietary Supplement      75854-321-30

30 Tablets      Sugar Free

Lactose Free

Niferex<sup>☐</sup>™

www.niferexrx.com      tablets

<p><b>Supplement Facts</b>                  Serving Size: 1 tablet                  Amount per Serving: <small>Percent Daily Value</small></p> <table border="1"> <tr> <td>Iron (as Sumalate® (ferrous asparto glycinate 50 mg) and polysaccharide iron complex 100 mg)</td> <td>150 mg</td> <td>83%</td> </tr> <tr> <td>Vitamin C (as ascorbic acid)</td> <td>60 mg</td> <td>100%</td> </tr> <tr> <td>Folate (as 1.4 mg Quatrefolic® (5S)-5, methyltetrahydrofolate glucuronate salt molar equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg)</td> <td>1 mg</td> <td>250%</td> </tr> <tr> <td>Vitamin B12 (as cyanocobalamin)</td> <td>25 mcg</td> <td>417%</td> </tr> <tr> <td>Zinc (as zinc-bisglycinate chelate)</td> <td>15 mg</td> <td>100%</td> </tr> <tr> <td>Succinic Acid</td> <td>50 mg</td> <td>†</td> </tr> <tr> <td>Dissolved Stomach Substance</td> <td>100 mg</td> <td>†</td> </tr> </table> <p>† Daily Value (DV) not established.</p> <p><b>OTHER INGREDIENTS:</b> Dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, vegetable stearate, silicon dioxide.</p>	Iron (as Sumalate® (ferrous asparto glycinate 50 mg) and polysaccharide iron complex 100 mg)	150 mg	83%	Vitamin C (as ascorbic acid)	60 mg	100%	Folate (as 1.4 mg Quatrefolic® (5S)-5, methyltetrahydrofolate glucuronate salt molar 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	†	Dissolved Stomach Substance	100 mg	†	<p>Rx Only Dietary Supplement                  30 Tablets</p> <p>75854-321-30                  SUGAR FREE                  LACTOSE FREE</p> <p><b>Niferex<sup>☐</sup>™</b>                  www.niferexrx.com      tablets</p> <p><i>Ferrous asparto glycinate and polysaccharide iron complex</i></p>	<p><b>DOSEAGE AND ADMINISTRATION:</b> One tablet daily, or as directed by a physician. See package insert for full prescribing information.</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b></p> <p><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.]</p> <p><b>MANUFACTURED FOR:</b> Avion Pharmaceuticals, LLC                  Alpharetta, GA 30022 1-888-61-AVION                  Rev. 0317-01 AV-384</p> <p><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.</p>	
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**NIFEREX**

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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:GW895810WR)	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: 70097M6B0)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color	brown (copper colored)	Score	no score	
Shape	ROUND	Size	19mm	
Flavor		Imprint Code	NxFE	
Contains				
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	01/23/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/23/2017		

**Labeler** - Avion Pharmaceuticals, LLC (965450542)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		965450542	manufacture(75854-321)

Revised: 3/2017

Avion Pharmaceuticals, LLC