# FERIVA 21 7- ascorbic acid, zinc glycinate, cyanocobalamin, ferrous asparto glycinate, folic acids and succinic acid tablet

Avion Pharmaceuticals, LLC

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FeRiva 21/7 Rx Only Dietary Supplement

#### DESCRIPTION

FeRiva 21/7<sup>®</sup> tablets for oral administration is a 28-day iron supplement regimen that consists of 21 red, oval-shaped iron tablets and 7 purple, oval-shaped placebo tablets. Each red, oval-shaped iron tablet is debossed with "21" and "7" separated by a line in the middle on the top-side of the tablet and blank on the other side. Each purple, oval shaped placebo tablet is blank on both sides of the tablet.

<b>Supplement Facts</b> Serving Size: 1 tablet		% Daily	% Daily Value for Pregnant &	
		Value	Lactating Women	
<b>Each Red Iron Tablet Conta</b>	ins:			
Vitamin C (as Ascorbic Acid)	175 mg	292%	292%	
Zinc (as Zinc Bisglycinate)	10 mg	67%	67%	
Vitamin B <sub>12</sub> (as Cyanocobalamin)	12 mcg	200%	150%	
Iron (as Ferrrous Asparto Glycinate) Sumalate®	75 mg	417%	417%	
Folate (as ((6S)-N5-methyltetrahydrofolic acid calcium salt (molar equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1 mg	250%	125%	
Succinic Acid	150 mg	†	†	
† Daily Value (DV) not established.				
PURPLE PLACEBO TABLE ingredients. Please see OTHE ingredients.				

# OTHER INGREDIENTS (RED IRON TABLETS)

Croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, and stearic acid. Coating contains: FD&C Red #40, HMPC, titanium dioxide and triacetin.

#### OTHER INGREDIENTS (PURPLE PLACEBO TABLETS)

Croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, and stearic acid. Coating contains: HMPC, titanium dioxide, triacetin, and FD&C Red #3, FD&C Blue #1.

## **INDICATIONS**

FeRiva 21/7<sup>®</sup> is a multivitamin/multimineral dietary supplement indicated for use in improving the nutritional status of patients with iron deficiency.

#### CONTRAINDICATIONS

FeRiva 21/7® is contraindicated in patients with a known hypersensitivity to any of the ingredients. Hemochromatosis and hemosiderosis are contraindicated to iron therapy.

#### **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.

#### **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. While prescribing this nutritional supplement for pregnant women, nursing mothers or for women prior to conception, their medical condition and other drugs, herbs and/or supplements consumption should be considered.

#### ADVERSE REACTIONS

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

### DOSAGE AND ADMINISTRATION

Usual dosage is one tablet daily with or without food or as prescribed by your healthcare provider. The FeRiva 21/7<sup>®</sup> Tablets blister pack supplies a 28-day course of iron therapy that consists of 21 red iron tablets and 7 purple placebo tablets. Take 1 red iron tablet daily for 21 days, followed by 1 purple placebo tablet daily for 7 days. After 28 tablets have been taken a new course may be started if prescribed.

#### **HOW SUPPLIED**

FeRiva 21/7<sup>®</sup> tablets blister pack (75854-318-28) contains 21 red iron tablets and 7 purple placebo tablets. 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 health insurance computer systems.

Keep out of reach of children. Store between 20°- 25°C (68°- 77°F).

Sumalate<sup>®</sup> 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.

Avion Pharmaceuticals, LLC Alpharetta, GA 30022 1-888-61-AVION L-0057 Rev. 1219-02

#### PRINCIPAL DISPLAY PANEL - 28 tablet container label

75854-318-28 RX ONLY

FeRiva 21/7

#### IRON SUPPLEMENT

Unique, Innovative Iron Supplementation System

• Enhanced GI Tolerability • Improved Absorption • Easy-to-swallow tablets

Once Daily 28-DAY IRON SUPPLEMENT REGIMEN

Avion



# **FERIVA 21 7**

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

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:75854-318
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	175 mg	
ZINC GLYCINATE (UNII: 681VJX72FE) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLYCINATE	10 mg	
CYANO COBALAMIN (UNII: P6 YC3EG204) (CYANOCOBALAMIN - UNII:P6 YC3EG204)	CYANOCOBALAMIN	12 ug	
<b>FERROUS ASPARTO GLYCINATE</b> (UNII: H7426 RGB3L) (FERROUS CATION - UNII: GW8958 10 WR)	FERROUS CATION	75 mg	
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg	
SUCCINIC ACID (UNII: AB6MNQ6J6L) (SUCCINIC ACID - UNII:AB6MNQ6J6L)	SUCCINIC ACID	150 mg	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NHRIC:75854-318-28	28 in 1 CARTON			
1		1 in 1 BLISTER PACK			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		10/20/2014	

Supplement Facts			
Serving Size:		Serving per Container :	
	<b>Amount Per Serving</b>	% Daily Value	
color			
color			
scoring	1		
shape			

size (solid drugs)	7 mm	
imprint		

# **Labeler** - Avion Pharmaceuticals, LLC (040348516)

Establishment			
Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-318)

Revised: 1/2021 Avion Pharmaceuticals, LLC