ACTIVE FE- .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, iron pentacarbonyl, magnesium oxide, zinc oxide, and cupric oxide tablet
Allegis Pharmaceuticals, LLC

Active FE™

Iron Supplement
Rx

Supplement Facts **Serving Size: 1 Tablet**	**Servings per container: 30**	
	Amount Per Serving:	**% Daily Value**
Vitamin A (as beta-carotene)	2100 IU	42%
Vitamin C (as ascorbic acid)	160 mg	267%
Vitamin D3 (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha-tocopheryl acetate)	40 IU	133%
Thiamin (Vitamin B1 as thiamin HCl)	4 mg	267%
Riboflavin (Vitamin B2)	4 mg	235%
Niacin (as niacinamide)	20 mg	100%
Vitamin B6 (as pyridoxine HCl)	20 mg	1000%
Folate (as folic acid)	1250 mcg	313%
Vitamin B12 (as cyanocobalamin)	30 mcg	500%
Iron (as carbonyl iron)	75 mg	417%
Magnesium (as magnesium oxide)	30 mg	8%
Zinc (as zinc oxide)	20 mg	133%
Copper (as cupric oxide)	1 mg	50%

OTHER INGREDIENTS

Coating (FD&C Blue#2 Lake, FD&C Red#40 Lake, FD&C Yellow#6 Lake, hydroxypropyl methylcellulose, polyvinyl alcohol, talc, titanium dioxide, triacetin), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silica, silicon dioxide, and stearic acid.

Professional Labeling

CLINICAL PHARMACOLOGY

Iron is an essential component in the formation of hemoglobin. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes that are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid, by dihydrofolate reductase. Vitamin B_{12} is required for the maintenance of normal erythropoiesis, nucleoprotein and myelin synthesis, cell reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of vitamin B_{12} from the gastrointestinal tract.

INDICATIONS AND USAGE

ACTIVE FE™ is an oral prescription multi-vitamin/multi-mineral dietary supplement for the use in improving the nutritional status of patients with iron deficiency. [1]

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[1] This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease.

CONTRAINDICATIONS

ACTIVE FE™ is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemolytic anemia, hemochromatosis and hemosiderosis are contraindications to iron therapy.

WARNINGS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient.

WARNING Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.** In case of accidental overdose, call a doctor or poison control center immediately.

Call your doctor about side effects. You may report side effects by calling Allegis Pharmaceuticals, LLC at **1-866-633-9033.**

PRECAUTIONS

General

Do not exceed recommended dose. The type of anemia and the underlying cause or causes should be determined before starting therapy with ACTIVE FE™. Since the anemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

Folic Acid

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies on this product have not been performed in subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious and start at the lower end of the dosing range.

ADVERSE REACTIONS

Adverse reactions with iron therapy may include GI irritations, constipation, diarrhea, nausea, vomiting, dark stools and abdominal pain. Adverse reactions with iron therapy are usually transient. Allergic

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

Carbonyl iron based products may decrease the absorption of medicines. Talk to your doctor and pharmacist before taking carbonyl products if you take any prescription or over-the-counter medicines.

OVERDOSAGE

The clinical course of acute iron overdosage can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, tarry stools melena, hematemesis, hypotension, tachycardia, metabolic acidosis, hyperglycemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma.

DIRECTIONS

Adults

Take one tablet daily, or as prescribed by a licensed medical practitioner.

Children under 12

Consult a doctor.

Pregnant or Nursing

Consult a doctor.

DO NOT EXCEED THE RECOMMENDED DOSE.

HOW SUPPLIED

ACTIVE FE™ is supplied as red capsule shaped tablets with imprint FE1 in child-resistant bottles containing 30 tablets. (28595-433-30[2])

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[2] This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels (AUG 2 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B12 deficiency (pernicious anemia). Based on our assessment of the risk of obscuring pernicious anemia, this product requires licensed medical supervision, an Rx status, and a National Drug Code (NDC) – or similarly-formatted product code, as required by pedigree reporting requirements and supply-chain control as well as – in some cases, for insurance-reimbursement applications.All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] Protect from light and moisture. Dispense in a tight, light-resistant container.

KEEP OUT OF REACH OF CHILDREN.

Rx
MADE IN CANADA

MANUFACTURED FOR:
Allegis Pharmaceuticals, LLC
Canton, MS 39046

Rev. 01/2016
Covered by U.S. Patent# 7998500

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

28595-433-30

ACTiVE FE™

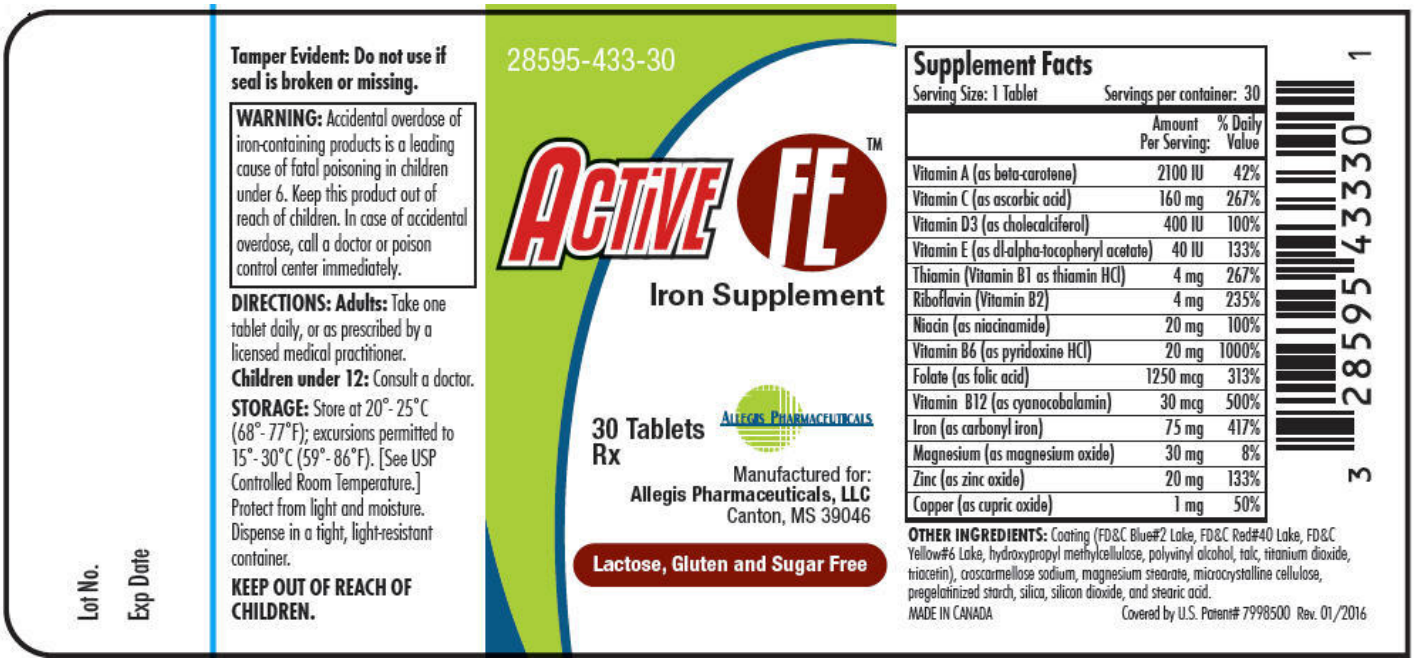
Iron Supplement

ALLEGIS PHARMACEUTICALS

30 Tablets
Rx

Manufactured for:
Allegis Pharmaceuticals, LLC
Canton, MS 39046

Lactose, Gluten and Sugar Free



ACTIVE FE

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, iron pentacarbonyl, magnesium oxide, zinc oxide, and cupric oxide tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:28595-433
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	2100 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	160 mg

CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	40 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	4 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1250 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	30 ug
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	75 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	30 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TRIACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:28595-433-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/18/2016	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving	% Daily Value

color	
scoring	1
shape	
size (solid drugs)	18 mm
imprint	

Labeler - Allegis Pharmaceuticals, LLC (792272861)

Revised: 1/2016 Allegis Pharmaceuticals, LLC