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
GM Pharmaceuticals, Inc.

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.

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 Yellow#6 Lake, FD&C Blue#2 Lake, FD&C Red#40 Lake, hydroxypropyl methylcellulose, polyvinyl alcohol, triacetin, talc, titanium dioxide), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide, silica, 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 indicated for the prevention and treatment of iron deficiency anemia and/or nutritional megaloblastic anemias.[1]

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1 This statement has not been evaluated by the Food and Drug Administration. 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 GM Pharmaceuticals, Inc. at **1-888-535-0305.**

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. (58809-725-30)

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: **GM Pharmaceuticals, Inc.**
Arlington, TX 76015

Rev. 05/2014

Covered by U.S. Patent# 7998500

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

58809-725-30

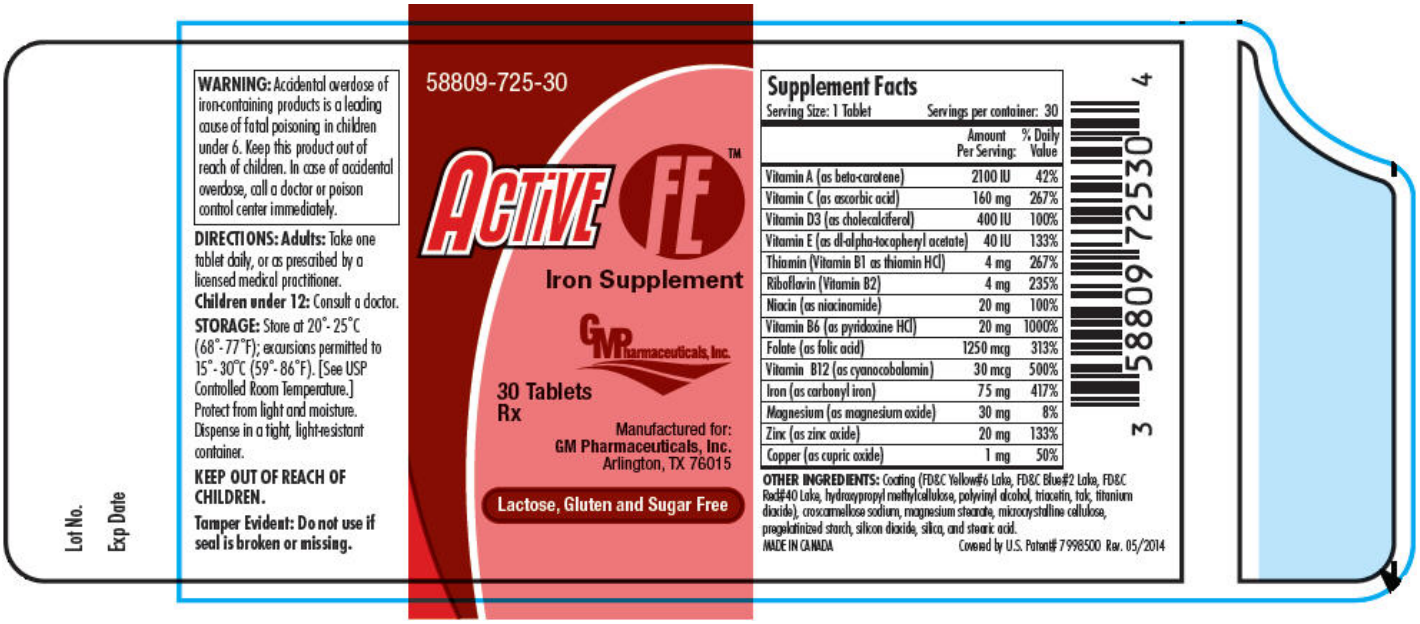
ACTiVE FE™
Iron Supplement

GMPharmaceuticals, Inc.

30 Tablets
Rx

Manufactured for:
GM Pharmaceuticals, Inc.
Arlington, TX 76015

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	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58809-725
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)	

Product Characteristics

Color	RED	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	FE1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-725-30	1 in 1 CARTON		
1		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/11/2013	

Labeler - GM Pharmaceuticals, Inc. (793000860)

Revised: 8/2014 GM Pharmaceuticals, Inc.