FINAZOL- ferrous fumarate, folate tablet
PureTek Corporation

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.

Finazol

DESCRIPTION:

Full Prescribing Information:
DESCRIPTION:
Active Ingredients:
Each caplet contains:
Vitamin A (as Retinyl Acetate) .....1500 mcg RAE
Vitamin C (as Ascorbic Acid) .....200 mg
Vitamin D3 (as Cholecalciferol) .....10 mcg (400 IU)
Vitamin E (as DL-alpha Tocopheryl Acetate) .....45 mg
Thiamin (as Thiamine Mononitrate) .....3.25 mg
Riboflavin (as Vitamin B2) .....3.35 mg
Niacin (as Niacinamide).....22.5 mg
Vitamin B6 (as Pyridoxine HCl).....6 mg
Folate (as L-5-Methyltetrahydrofolate calcium salt) .....1700 mcg DFE
(1000 mcg as L-5-Methylfolate)
Vitamin B12 (as Methylcobalamin).....26 mcg
Biotin.....100 mcg
Pantothenic Acid (as Calcium Pantothenate).....15 mg
Calcium (as Calcium Carbonate).....100 mg
Iron (as Ferrous Fumarate).....18 mg
Iodine (as Potassium Iodide).....25 mcg
Magnesium (as Magnesium Oxide).....50 mg
Zinc (as Zinc Citrate).....30 mg
Selenium (as Selenomethionine).....30 mcg
Copper (as Copper Oxide).....1 mg
Manganese (as Manganese Sulfate).....0.75 mg
Chromium (as Chromium Polynicotinate).....37.5 mcg
Molybdenum (as Sodium Molybdate).....25 mcg
Potassium (as Potassium Chloride) .....24.5 mg
Boron (as Boron Citrate).....25 mcg

Other Ingredients: Crospovidone, Dextrin, Dextrose Monohydrate, FD&C Yellow #6/Sunset Yellow FCF Aluminum Lake, Magnesium Stearate, Microcrystalline Cellulose, Purified Stearic Acid, Silicon Dioxide, Sodium Carboxymethylcellulose, Titanium Dioxide.

INDICATIONS:

Finazol™ is indicated for iron deficiency anemia and folate deficiency as in extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss and advanced

age. Also, for conditions in which iron deficiency and vitamin C deficiency occur together, along with a deficient intake or increased need for B-Complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in convalescence.

CONTRAINDICATIONS:

This product is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folate may obscure its signs and symptoms.

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. Administration of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

Precautions:

Folate in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. There is a potential danger in administering folate to patients with undiagnosed anemia, since folate may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia. The patient's medical conditions and consumption of other drugs, herbs, and / or supplements should be considered.

For use on the order of a licensed healthcare practitioner.
Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873** or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions:

Finazol™ is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin or Clopidogrel).

Adverse Reactions:

Folate: Allergic sensitizations have been reported following both oral and parenteral administration of folate.

Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving **Finazol™** after meals may control occasional gastrointestinal disturbances. **Finazol™** is best absorbed when taken at bedtime. Adverse reactions have been reported with

specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

OVERDOSE:

Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. **Finazol™** should be stored beyond the reach of children to prevent against accidental iron poisoning.

Treatment:

For specific therapy, exchange transfusion and chelating agents should be used. For general management, gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

DOSAGE AND ADMINISTRATION:

Adults (persons over 12 years of age) take one (1) **Finazol™** caplet daily, between meals or as directed by a licensed healthcare practitioner. Do not administer to children under the age of 12.

HOW SUPPLIED:

Finazol™ are yellow with slightly brown speckled, oblong, coated caplets. Each bottle contains 30 caplets – NDC 59088-008-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

STORAGE:

Do not use if bottle seal is broken.

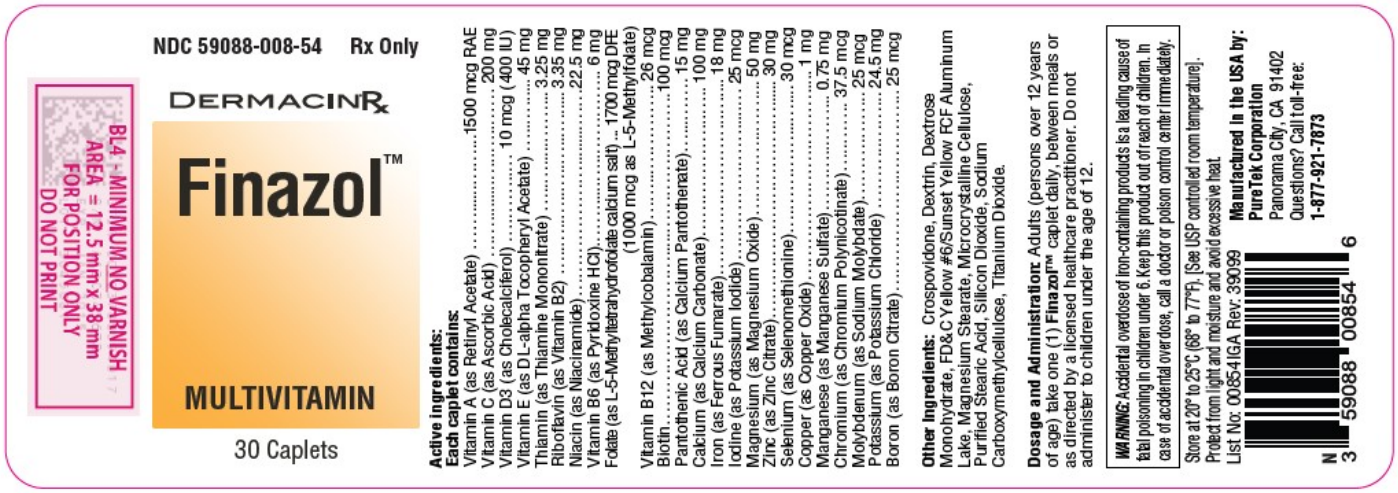
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Store at 20° to 25°C (68° to 77°F). [See USP controlled room temperature]. Protect from light and moisture and avoid excessive heat. To report a serious adverse event or to obtain product information, contact **877-921-7873.**

Finazol

Manufactured by:
PureTek Corporation
Panorama City, CA 91402
For questions or information

call toll-free: **877-921-7873**



FINAZOL

ferrous fumarate, folate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	200 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	45 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3.25 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.35 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	22.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	6 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1000 ug
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	26 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	100 ug
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	15 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	100 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	18 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	25 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	50 mg
ZINC CITRATE (UNII: K72I3DEX9B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	30 mg
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	30 ug
CUPROUS OXIDE (UNII: T8BEA5064F) (CUPROUS OXIDE - UNII:T8BEA5064F)	CUPROUS OXIDE	1 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+))	MANGANESE CATION	

MANGANESE SULFATE (UNII: W00LYS4126) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	0.75 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (NIACIN - UNII:2679MF687A)	CHROMIUM NICOTINATE	37.5 ug
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	25 ug
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	24.5 mg
BORON (UNII: N9E3X5056Q) (BORON - UNII:N9E3X5056Q)	BORON	25 ug

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	yellow (With Slightly Brown Specks)	**Score**	no score
Shape	CAPSULE (Oblong Caplet)	**Size**	22mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-008-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/11/2024	

Labeler - PureTek Corporation (785961046)

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