

**PROMETA- ferrous fumarate, folic acid tablet**  
**PRENATRYL- ferrous fumarate, folic acid 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.*

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**Prometa & Prenatryl**

**DESCRIPTION:**

**Full Prescribing Information:**

**Each caplet contains:**

Vitamin A (as retinyl acetate).....	1500 mcg (5000 IU)
Vitamin C (as ascorbic acid).....	120 mg
Vitamin D3 (as cholecalciferol).....	20 mcg (800 IU)
Vitamin E (dl-alpha tocopheryl acetate).....	30 mg (30 IU)
Thiamin (as thiamine mononitrate).....	3 mg
Riboflavin (vitamin B2).....	3.4 mg
Niacin (as niacinamide).....	20 mg
Vitamin B6 (as pyridoxine hydrochloride).....	50 mg
Folate (as folic acid).....	1700 mcg DFE (1000 mcg folic acid)
Vitamin B12 (as cyanocobalamin).....	10 mcg
Choline (as choline bitartrate).....	55 mg
Calcium (as calcium carbonate).....	200 mg
Iron (as ferrous fumarate).....	27 mg
Iodine (as potassium iodine).....	150 mcg
Magnesium (as magnesium oxide).....	200 mg
Zinc (as zinc oxide).....	25 mg
Selenium (as selenium amino acid chelate).....	70 mcg
Manganese (as manganese sulfate).....	2.6 mg
Chromium (as chromium polynicotinate).....	45 mcg
Molybdenum (as molybdenum amino acid chelate).....	50 mcg

**Other Ingredients:**

Croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid, Clear coating: (hydroxypropyl methylcellulose, PEG-8).

**Indications**

Indicated to provide vitamins and minerals to women throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years.

May be beneficial in improving the nutritional status of women prior to conception.

## **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 folic acid 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 B<sub>12</sub> is deficient.

### **Precautions**

Folic acid 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 folic acid to patients with undiagnosed anemia, since folic acid 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 B<sub>12</sub> 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 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](http://www.fda.gov/medwatch).

## **Drug Interactions:**

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:**

Folic Acid: Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.

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 after meals may control occasional gastrointestinal disturbances. It 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. Multivitamins should be stored beyond the reach of children to prevent against accidental iron poisoning. **Keep this and all other drugs out of reach of children.**

### **Treatment:**

For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform 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) One (1) caplet daily, between meals, or as directed by a physician. Do not administer to children under the age of 12.

### **HOW SUPPLIED**

**Prometa™** are beige speckled, oblong, coated caplets in bottles containing 30 caplets – NDC 59088-172-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

**Prenatryl™** are beige speckled, oblong, coated caplets in bottles containing 30 caplets – NDC 59088-169-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

### **Storage**

**Do not use if bottle seal is broken.**

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

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP].

Protect from light and moisture and avoid excessive heat.

To report a serious adverse event or to obtain product information, contact **1-877-921-7873**.

**Prometa™**

**Manufactured in the USA by:**

**PureTek Corporation**

Panorama City, CA 91402

Questions? Call toll-free:

**1-877-921-7873**

NDC 59088-172-54 Rx Only



30 Caplets

**Supplement Facts**

Serving Size: 1 Caplet  
30

Amount Per Serving: %DV for Pregnant and Lactating Women

Vitamin A (as retinyl acetate)	1500 mcg	115%
Vitamin C (as ascorbic acid)	120 mg	100%
Vitamin D <sub>3</sub> (as cholecalciferol)	20 mcg	133%
Vitamin E (dl-alpha tocopheryl acetate)	30 mg	158%
Thiamin (as thiamine mononitrate)	3 mg	214%
Riboflavin (Vitamin B <sub>2</sub> )	3.4 mg	213%
Niacin (as niacinamide)	20 mg	111%
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	50 mg	2500%
Folate (as folic acid) 1700 mcg DFE (1000 mcg folic acid)	283%	
Vitamin B <sub>12</sub> (as cyanocobalamin)	10 mcg	357%
Choline (as choline bitartrate)	55 mg	10%
Calcium (as calcium carbonate)	200 mg	15%
Iron (as ferrous fumarate)	27 mg	100%
Iodine (as potassium iodine)	150 mcg	52%
Magnesium (as magnesium oxide)	200 mg	50%
Zinc (as zinc oxide)	25 mg	192%
Selenium (as selenium amino acid chelate)	70 mcg	100%
Manganese (as manganese sulfate)	2.6 mg	100%
Chromium (as chromium polynicotinate)	45 mcg	100%
Molybdenum (as molybdenum amino acid chelate)	50 mcg	100%

**Other Ingredients:** Croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid. Clear coating: (hydroxypropyl methylcellulose, PEG-8).

**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.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

List No: 17254JPA Rev. 38230-01



Manufactured in the USA by:  
PureTek Corporation  
Panorama City, CA 91402  
Questions? Call toll-free:  
1-877-921-7873

N 3 59088 17254 14

**Prenatryl™**

**Manufactured in the USA by:**

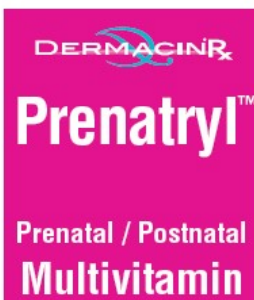
**PureTek Corporation**

Panorama City, CA 91402

Questions? Call toll-free:

**1-877-921-7873**

NDC 59088-169-54 Rx Only



30 Caplets

**Supplement Facts**

Serving Size: 1 Caplet  
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Amount Per Serving: %DV for Pregnant and Lactating Women

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**Other Ingredients:** Croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid. Clear coating: (hydroxypropyl methylcellulose, PEG-8).

**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.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

List No: 16954JPA Rev. 38202



Manufactured in the USA by:  
PureTek Corporation  
Panorama City, CA 91402  
Questions? Call toll-free:  
1-877-921-7873

N 3 59088 16954 14

# PROMETA

ferrous fumarate, folic acid tablet

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-172
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
<b>MANGANESE SULFATE</b> (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	2.6 mg
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	50 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
<b>MOLYBDENUM</b> (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	50 ug
<b>CHOLINE BITARTRATE</b> (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	55 mg
<b>SELENIUM</b> (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	70 ug
<b>CHROMIUM NICOTINATE</b> (UNII: A150AY412V) (CHROMIUM CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	45 ug
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 ug

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	brown (beige speckled caplets)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-172-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/11/2021	

## PRENATRYL

ferrous fumarate, folic acid tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-169
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
<b>MANGANESE SULFATE</b> (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	2.6 mg
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	50 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg

<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
<b>MOLYBDENUM</b> (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	50 ug
<b>CHOLINE BITARTRATE</b> (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	55 mg
<b>SELENIUM</b> (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	70 ug
<b>CHROMIUM NICOTINATE</b> (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	45 ug
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	brown (beige speckled caplets)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-169-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/30/2020	

**Labeler** - PureTek Corporation (785961046)