PRENATOL-M- multivitamin 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.

Prenatol-M

DESCRIPTION:

Each caplet contains:
Vitamin A (as Retinyl Acetate) ..... 1500 mcg RAE
Vitamin C (as Ascorbic Acid) ..... 120 mg
Vitamin D3 (as Cholecalciferol)..... 20 mcg (800 IU)
Vitamin E (as Dl-Alpha Tocopheryl Acetate) ..... 13.5 mg
Thiamin (as Thiamine Mononitrate) ..... 3 mg
Riboflavin ..... 3.4 mg
Niacin (as Niacinamide) ..... 20 mg
Vitamin B6 (as Pyridoxine Hydrochloride) ..... 50 mg
Folate (as L-5-Methyltetrahydrofolate calcium salt) ..... 2040 mcg DFE
(1200 mcg as L-5-Methylfolate)
Vitamin B12 (as Methylcobalamin) ..... 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, Coating: Hydroxypropyl Methylcellulose [HPMC], PEG-8.

Indications and Usage: Prenatol-M™

Indications and Usage: Prenatol-M™ is 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.

Prenatol-M™ 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 folate may obscure its signs and symptoms.

Warnings:

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. In case of accidental overdose, call a doctor or poison control center immediately. Administration of folate 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 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 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:

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

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:

Prenatol-M™ caplet daily, between meals or as directed by a licensed healthcare practitioner. Do not administer to children under
the age of 12.

How Supplied:

Prenatol-M™ are beige speckled, oblong, coated caplets, supplied in a bottle containing 30 caplets (NDC 59088-009-54). Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

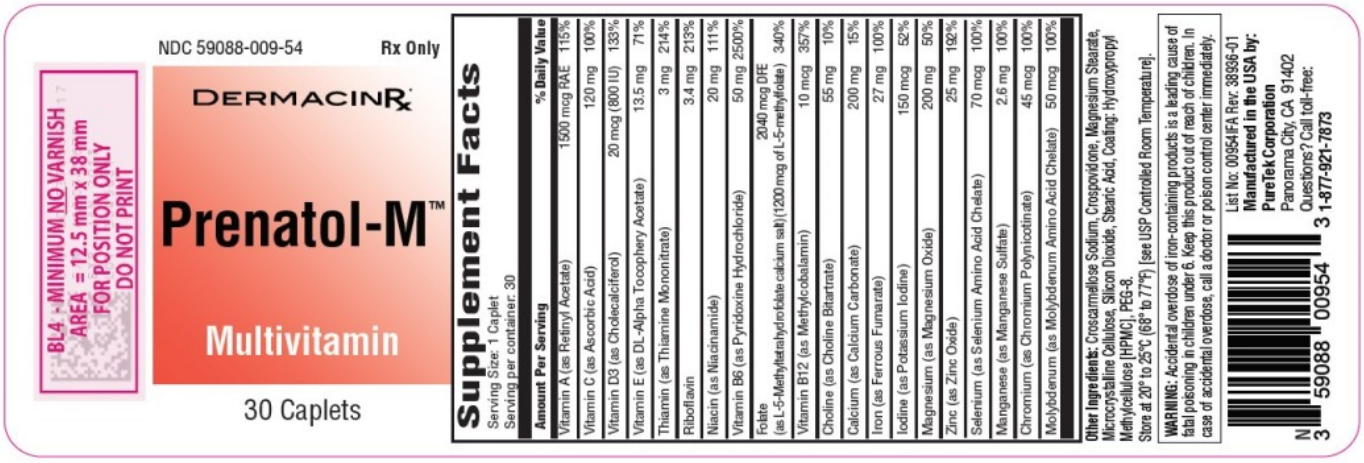
Storage

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].

Prenatol-M™

Manufactured in the USA by:

PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**



PRENATOL-M

multivitamin tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	50 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	55 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	13.5 mg
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	70 ug
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	50 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	200 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	45 ug
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANOUS CATION - UNII:H6EP7W5457)	MANGANOUS CATION	2.6 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 ug
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	10 ug
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	2040 ug

THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSPOVIDONE (UNII: 2S7830E561)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	brown (Beige, Speckled)	**Score**	no score
Shape	CAPSULE (Oblong)	**Size**	22mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-009-54	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/06/2024	

Labeler - PureTek Corporation (785961046)

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