

PRENATAL PLUS IRON- multivitamin/multimineral supplement tablet, film coated
Blenheim Pharmacal, 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.

Prenatal Plus Iron Tablets

DESCRIPTION

Prenatal Plus Iron Tablet is caplet shaped, film coated tablet debossed CIS 28, and provides 10 vitamins and 4 minerals to supplement the diet before, during and after pregnancy.

Each Prenatal Plus tablet Contains:

Vitamin A (Acetate and Beta Carotene).....	4000 I.U.
Vitamin C (Ascorbic acid).....	120 mg
Vitamin D-3 (Cholecalciferol).....	400 I.U.
Vitamin E (dl- Alpha Tocopheryl Acetate).....	22 I.U.
Thiamine (Vitamin B-1 from Thiamine Mononitrate.....	1.84 mg
Riboflavin (Vitamin B-2).....	3 mg
Niacin(Niacinamide).....	20 mg
Vitamin B-6 (Pyridoxine HCl).....	10 mg
Folic Acid.....	1 mg
Vitamin B-12 (Cyanocobalamin).....	12 mcg
Calcium (Calcium Carbonate).....	200 mg
Iron (Carbonyl Iron).....	29 mg
Zinc (Zinc Oxide).....	25 mg
Copper (Cupric Oxide).....	2 mg

Other ingredients: Ascorbyl Palmitate, Citric Acid anhydrous, DL-alpha Tocopherol, Ethylcellulose, FD&C Blue #2 lake, FD&C Red #40 lake, FD&C Yellow # 5 lake, FD&C Yello # 6 lake, Glucose, Gum Acacia, Hypromellose, Magnesium Stearate, Maize Starch, Maltodextrin, Methylcellulose, Microcrystalline Cellulose, Mineral Oil, Mono-and di-glycerides, Polyethyelene Glycol, Pregelatinized Corn Starch, Silicon Dioxide, Sorbic Acid, Soy Protein, Stearic Acid, Sucrose, Titanium Dioxide, Tricalcium Phosphate

INDICATIONS

To provide Vitamin and Mineral supplementation throughout pregnancy and during the postnatal period for both the lactating and non lactating mother. It is also useful for improving nutritional status prior to conception

DOSAGE

As a dietary adjunct before, during and after pregnancy, take one tablet daily with a meal, or as directed by a physician.

WARNING

Warning: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under age 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Precautions: Folic acid may partially correct the hematological damage due to Vitamin B12 deficiency of pernicious anemia, while the associated neurological damage progresses.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yello No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

STORAGE

Store at room temperature. Dispense in a well closed light resistant container with a child resistant cap.

HOW SUPPLIED

NDC 0904-5339-60 plastic bottle containing 100 Tablets.

Principal Display Panel

Prenatal Plus Iron Tablets (Multivitamin/Multimineral Supplement)

31 Tablets

10544-609-31

NDC: 10544-609-31 LCN#: 00
MFG: 0904-5339-60

**Prenatal Plus Iron Tablets, Multivitamin/
Multimineral Supplement**

31 Tablets
Rx Only
Dosage: See package insert
Store at room temperature.
Store in a tight, light-resistant container
(See USP). Keep out of the reach of
children.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under age 6. In case of accidental overdose, call a doctor or Poison Control Center immediately.

Dist. By: Major Pharmaceuticals,
Livonia, MI 48150
Repackaged By: Blenheim Pharmaceutical, Inc.,
North Blenheim, NY 12131
Lot #: BP00000000
Exp. Date: 00/00/0000

Prenatal Plus Iron Tablets, Multivitamin/
Multimineral Supplement 31 Tablets
NDC: 10544-609-31 MFG: 0904-5339-60
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PRENATAL PLUS IRON

multivitamin/multimineral supplement tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10544-609(NDC:0904-5339)
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	3080 [iU]
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	920 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	22 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE	1.84 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	29 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ETHYLCELLULOSE (100 MPA.S) (UNII: 47MLB0F1MV)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
ACACIA (UNII: 5C5403N26O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLCELLULOSE (1500 MPA.S) (UNII: P0NTE48364)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
METHYL SORBATE (UNII: J3048615R1)	
SOY PROTEIN (UNII: R44IWB3RN5)	

Product Characteristics

Color	YELLOW (TAN)	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	CIS28
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10544-609-31	31 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/17/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/17/2010	

Labeler - Blenheim Pharmacal, Inc. (171434587)**Registrant** - Blenheim Pharmacal, Inc. (171434587)**Establishment**

Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	repack(10544-609)

Revised: 1/2016

Blenheim Pharmacal, Inc.