

PRENATAL PLUS - vitamin a acetate, beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, zinc oxide, cupric oxide 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 Vitamin and Mineral Tablet is an Tan-Yellow colored, modified oval biconvex film coated tablet debossed G12 on one side, 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 mg
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 (Ferrous Fumarate).....	27 mg
Zinc (Zinc Oxide).....	25 mg
Copper (Cupric Oxide).....	..2 mg

Other ingredients: Ascorbyl Palmitate, Butylated Hydroxytoluene, Croscarmellose sodium, Dicalcium phosphate Dihydrate, DL-alpha-tocopherol, FD&C Blue # 2 lake, FD&C Red # 40, FD&C Red # 40 lake, FD&C yellow # 5, FD&C yellow # 6, FD&C yellow # 6 lake, Gelatin, Hypromellose, Magnesium stearate, Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized corn starch, Propylene Glycol, Silica, Sodium Ascorbate, Sodium Benzoate, Sorbic Acid, Starch, Stearic Acid, Sucrose, SUNflower Oil, Titanium dioxide, Triacetin, Triglycerides.

Indication

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: 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.

STORE AT CONTROLLED ROOM TEMPERATURE 15⁰ - 30⁰C (59⁰ - 86⁰F). AVOID EXCESS HEAT.

Prenatal Plus Vitamin and Mineral Tablet

NDC 65162-668-10: Plastic bottle containing 100 Tablets

NDC 65162-668-50: Plastic bottle containing 500 Tablets

Dispense in a well closed light-resistant container, with a child resistant container.



10544-549-31 - Bottle Label

PRENATAL PLUS

vitamin a acetate, beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, zinc oxide, cupric oxide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10544-549(NDC:65162-668)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	3080 [iU]
BETA CAROTENE (UNII: 01YAE03M7J) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	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 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)	THIAMINE	1.84 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACIN - UNII:2679MF687A)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	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
FERROUS FUMARATE (UNII: R5L488RY0Q) (IRON - UNII:E1UOL152H7)	IRON	27 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (COPPER - UNII:789U1901C5)	COPPER	2 mg

Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
ALPHA-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBATE (UNII: S033EH8359)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	yellow (Tan-Yellow)	Score	no score
Shape	OVAL (Modified Oval Biconvex)	Size	19mm

Flavor		Imprint Code	G12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10544-549-31	31 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/09/2010	

Labeler - Blenheim Pharmacal, Inc. (171434587)

Registrant - Blenheim Pharmacal, Inc. (171434587)

Establishment

Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	repack